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Published in:
Danish Medical Journal

Publication date:
2019

Document version
Publisher's PDF, also known as Version of record

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Citation for published version (APA):
Thinggaard, E., Bjerrum, F., Strandbygaard, J., Konge, L., & Gögenur, I. (2019). A randomised clinical trial of take-home laparoscopic training. *Danish Medical Journal*, 66(1), [A5525]. <https://ugeskriftet.dk/dmj/randomised-clinical-trial-take-home-laparoscopic-training>

A randomised clinical trial of take-home laparoscopic training

Ebbe Thinggaard^{1,2}, Flemming Bjerrum^{1,2}, Jeanett Strandbygaard³, Lars Konge¹ & Ismail Gögenur²

ABSTRACT

INTRODUCTION: Simulation-based training in surgery helps trainees master laparoscopic skills, and training at home on mobile box trainers may allow trainees to reach proficiency faster. The aim of this study was to examine the added effects of training at home.

METHODS: Participants were trainees from departments of surgery, gynaecology and urology who were recruited while taking part in a laparoscopic training course. The intervention consisted of added access to a mobile box trainer allowing participants to train at home.

RESULTS: During a one-year study period, 36 participants completed the trial. There was no statistically significant difference in the number of days it took to complete the course (86 days versus 89 days, $p = 0.89$) or in the final test scores of the two groups (493 versus 460, $p = 0.07$). A significant difference in the number of training sessions attended was found (5.8 versus 2.3, $p < 0.001$). Participants were able to reliably rate their own performance; the intraclass correlation coefficient was 0.86, $p < 0.001$.

CONCLUSIONS: Trainees who had access to training at home did not pass a test earlier or achieve a higher score at the end of a course than trainees who had no such access. Improved access to training at home allowed for shorter and more frequent sessions; however, testing and mandatory training requirements apparently determine training patterns. Trainees were able to reliably rate their own performance.

FUNDING: Equipment for the study was provided by the Copenhagen Academy for Medical Education and Simulation, Capital Region of Denmark, Copenhagen, Denmark.

TRIAL REGISTRATION: The study was exempt from ethical approval according to Danish legislation (H-3-2014-FSP31). The trial protocol was registered with www.clinicaltrials.gov prior to commencing the trial (NCT02243215).

Training on simulators has become part of how we train surgeons. Simulation training has been shown to improve patient outcomes and is a valuable addition to the traditional method of training surgeons at the operating table [1]. Although many surgical trainees and their patients have benefitted from these developments, barriers to simulation training remain. Studies have identified barriers such as access to simulators, time for training and financial constraints [2]. To over-

come these barriers, simple mobile box trainers (BT) have been developed, which allow training at home at a time that suits the trainee [3]. Nonetheless, training at home without supervision poses new challenges [4]. Home training of laparoscopic skills has been shown to be feasible [5]. However, providing trainees with the freedom to organise their training could change training patterns, allowing for more distributed training where trainees practice more frequently at shorter intervals. A distributed approach to training is beneficial for technical skills acquisition [6], and is also in line with educational principles of deliberate practice [7] and directed self-regulated learning (DSRL) [8]. The purpose of the present study was to examine the added effects of training at home. We looked at the number of days it took to complete the training, time spent on training, number of training sessions and differences in final scores. Furthermore, we explored the participants' ability to rate their own performance when training without supervision using a structured self-rating system.

METHODS

Setting

At the Copenhagen Academy for Medical Education and Simulation [9], doctors in speciality training participate in a basic laparoscopic skills training programme during the first year of their training. The course is a cross-speciality training programme for doctors from departments of gynaecology, urology and surgery [10]. The aim of the course is to prepare the course participants for their first supervised laparoscopic surgical procedure. The course consists of two formalised one-day courses separated by a period of self-regulated training on virtual reality simulators (VRS) and BT. The first part of the programme is an introductory course, which includes theoretical teaching imparted as traditional classroom training mixed with practical sessions to prepare the trainees for training on VRS and BT. After the introduction course, the participants go through a period of self-regulated training during which they book training sessions at the simulation centre and practice on both VRS and BT. At the simulation centre, they are assisted by a simulator technician who is able to give technical assistance and provide

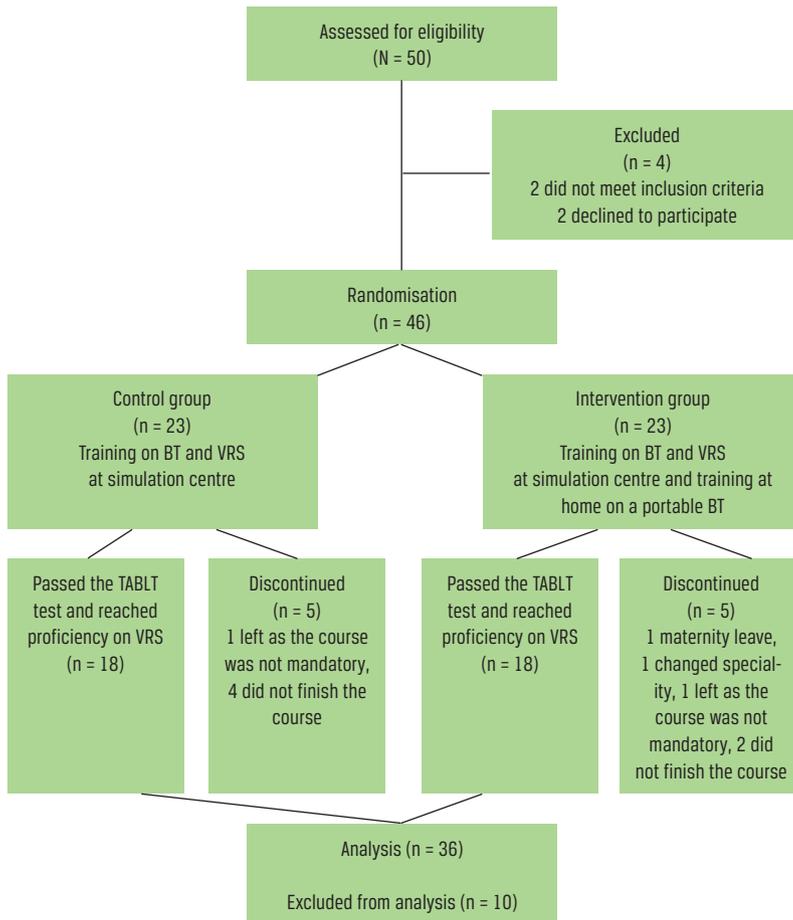
ORIGINAL ARTICLE

1) Copenhagen Academy for Medical Education and Simulation, Capital Region of Denmark
2) Department of Surgery, Zealand University Hospital, Koge
3) Department of Obstetrics and Gynaecology, Juliane Marie Centre, Rigshospitalet, Denmark

Dan Med J
2019;66(1):A5525

 **FIGURE 1**

Flow chart of participant enrolment.



BT = box trainer; TABLT = Training and Assessment of Basic Laparoscopic Techniques; VRS = virtual reality simulator.

feedback during training. Participants are required to pass the Training and Assessment of Basic Laparoscopic Techniques (TABLT) [11] test on the BT and to reach a predefined level of proficiency on the VRS. The TABLT test is a training and assessment system consisting of five simple tasks: peg-transfer, cutting, sharp dissection, blunt dissection and cyst removal. Each task has specified types of errors, and a pass/fail level has been set so that the goal is clear for the trainees. Rating is done using a simple scoring system based on time and number of errors [11]. Participants can rate their own performance when training on the TABLT and can see when they have reached the pass/fail level. When participants feel ready, they hand in a pre-test in which they rate their own performance. After handing in the pre-test they can book a time for a proctored test where a member of faculty is present during testing. After reaching proficiency on the VRS and passing the TABLT test, participants can sign up for a one-day operative course.

Participants

The course participants consisted of doctors in the first year of their speciality training. Participants who had performed more than fifty laparoscopic procedures were excluded.

Intervention

The intervention consisted of the addition of home training on a mobile BT. The intervention group trained at the simulation centre and were also given a portable BT [12] allowing them to practice at home. The control group trained at the simulation centre only. Both groups had access to training on VRS at the simulation centre.

Randomisation

The primary investigator (ET) was responsible for inclusion of participants. After enrolment, participants were randomly allocated using a computer-generated allocation sequence (randomiser). The administrator at the simulation centre retrieved the allocation sequence and kept the sequence concealed until the allocation had been finalised.

Outcomes

All participants were given a training log to record their training. Based on information from the logbooks, we looked at the number of days from enrolment to passing the TABLT test, the time spent training and the number of training sessions attended. We also explored differences in the performance levels that participants reached on their final TABLT test and recorded the participants' ability to rate themselves.

Statistical analysis

The sample size for the trial was calculated based on the assumption that the control group would pass the TABLT test after six weeks of practice (42 days), standard deviation (SD) ± 3 weeks (± 21 days). The intervention group was expected to pass after four weeks of practice (28 days), SD ± 3 weeks (± 21 days). Setting alpha at 0.05 and beta to 0.10, a total of 24 participants were required in each group. The trial was planned with a one-year inclusion period. Accounting for inaccuracies, we expected to include a total of 50 participants in the trial during the one-year study period during which six courses were planned with up to 72 course places. We used student's t-test to analyse whether there was a significant level of difference in the above-mentioned measurements. A p-value below 0.05 was considered statistically significant for the primary outcome. To determine the reliability of the self-rated test, we compared participants' ratings of their pre-test and the rating of a trained blinded rater. The intraclass correlation coefficient (ICC) was used to ex-

amine the reliability of the participants' self-rating. A statistical software package was used (SPSS vs. 20.0, Chicago, IL).

Trial registration: The trial was submitted for evaluation to the Regional Ethics Committee, which determined that no approval was needed for the trial (H-3-2014-FSP31). The trial was also registered with clinicaltrials.gov prior to its commencement (NCT02243215), and it was conducted according to the CONSORT statement [13].

RESULTS

We included participants during a one-year period in which 50 doctors participated in the training course. Out of the 50 participants who took part in the course, 46 were enrolled in the study and 36 completed the course within the one-year study period. Four participants dropped out of the training course, and six participants were excluded from the study as they did not complete the training course during the one-year study period. Out of the 36 who completed the course, 18 were from the control group, and 18 were from the intervention group, see **Figure 1**. For the participants' baseline characteristics, see **Table 1**. At the end of the one-year study period, we performed a new sample size calculation based on data available from the 36 participants, corresponding to 75% of the anticipated sample size. We found that 11,422 participants would be needed in each group which was not feasible, and therefore we decided to stop recruiting participants. We found no difference in the number of days from enrolment to the passing of the TABLT test (86 days versus 89 days, $p = 0.89$), time spent training on box trainers (302 minutes versus 218 minutes, $p = 0.26$) or between the test score (493 versus 460, $p = 0.07$) (**Table 2**). However, we did find a significant difference in the number of training sessions (5.8 versus 2.3, $p < 0.001$), see **Table 2**. There was a good reliability when comparing participants' ratings of their pre-test and that of a blinded rater, ICC 0.86, $p < 0.001$.

DISCUSSION

In this study, we explored the added effect of training laparoscopic skills at home and found no difference in the number of days or in the time spent training to pass the TABLT test. However, we did find a significant difference in the number of training sessions attended. Our trial shows that participants training at home do not complete the course faster than participants training only at the simulation centre. However, they practiced more frequently and at shorter intervals. Participants could reliably rate their own performance and 100% were able to pass the TABLT test on a pre-test

using a structured self-rating system. In this study, we found that easier access to training did not result in participants passing a test faster. Take-home training can be challenging to implement, and uptake among surgical trainees can be difficult [14]. We found that the duration of training in general was longer for the intervention group and that training patterns varied greatly among participants. These findings demonstrate that factors other than access to training are important determinants of the training duration and training patterns. The final part of the training programme was the operative course, which was held on fixed dates six times annually. Participants decided themselves when to enrol for the final course but did so before reaching proficiency on the VRS and before passing the TABLT test. This may have imposed a structure on training duration and patterns that influenced the self-regulated part of the training course, as the final course provided a deadline by when the TABLT test was to be passed. Accordingly, participants entered a training programme governed by the date of the final operative course. Distributing training in shorter and more frequent training sessions has been shown to improve training outcomes compared with massed training sessions [6]. Distributed training is recommended for laparo-

TABLE 1

Participants' baseline characteristics.

	Intervention group	Control group	Total
Participants, n	18	18	36
Age, yrs, median (range)	30 (25-36)	30 (25-46)	30 (25-46)
Gender, n			
Men/women	5/13	5/13	10/26
Speciality, n			
Surgery	6	5	11
Urology	3	3	6
Gynaecology	9	10	19
Dominant hand, n			
Right/left	16/2	16/2	32/4

TABLE 2

Training on box trainers.

	Group, mean (95%CI)		p-value
	intervention	control	p-value
Time to complete the course, days	86 (52-120)	89 (52-127)	0.89
Time spent training, min.	302 (189-414)	218 (112-223)	0.74
Training sessions, n	5.8 (4-7.5)	2.3 (1.5-3.1)	< 0.001
Final TABLT test score	493 (465-522)	460 (434-485)	0.63

CI = confidence interval; TABLT = Training and Assessment of Basic Laparoscopic Techniques.

scopic virtual reality simulator training [15], and learning curves, in particular, have been shown to improve by using distributed training compared with massed training [16]. Even though the ideal training interval for laparoscopic simulation training has not been established, it has been shown that short training intervals are superior to long training intervals [17]. The fact that participants with access to training at home did not reach a higher level on the test might be explained by the fact that they were instructed on how to rate their own performance during training. Therefore, they knew that it made sense for them to stop training when they reached a sufficient performance level. However, this was a deliberate choice of training strategy. Being able to rate your own performance allows for a more independent approach to training and has emerged from the instructional method called DSRL [8, 18], which is recommended for simulation training [19]. Principles of DSRL have shown to be useful in VRS mastoidectomy training [20]. This approach may also be of great value for training of laparoscopic skills at home. When considering unsupervised laparoscopic skills training at home, using DSRL as a strategy would allow for a structured training programme where trainees are in control of their training. In the present study, we showed that participants could reliably rate their own performance on the TABLT test. Being able to reliably rate your own test allows trainees to monitor their own training and provides them with a tool to apply self-regulatory skills.

Limitations

In this study, we chose to investigate the added effect of training at home on a simple mobile BT while also training in a simulation centre. As we did not wish to limit the participants' access to training, it was not possible to compare the effect of only using home-based training with that of training only at a simulation centre. Having chosen a different design could have given us insight into the effects of training at home versus training at a simulation centre. However, this was beyond the scope of our study. In our sample size calculation, we used a beta of 0.10. Having chosen a beta of 0.20 might have allowed for our inclusion of participants to match that of our sample size calculation. In our training programme, we use both VRS and BT; mixing two training methods could cloud findings. A trial focusing on BT exclusively might have more clearly demonstrated potential benefits of training at home using a BT. However, examining the use of training at home as a supplement was a deliberate choice of study design. We chose to do the study under realistic circumstances as part of an existing laparoscopic training programme. The results of our study could help guide others that may consider incorporating take-

home training in their laparoscopic training course. In the basic laparoscopy course, we also use a cross-specialty approach to laparoscopic training where doctors from different specialties practice together. Having participants from different specialties and with different levels of experience may have had an impact on the results. Using participants from different specialties increases the external validity as findings can be generalised across training programmes for different specialties. The participants in our study had different levels of experience prior to commencing the training programme. This makes the results of the trial applicable to trainees with different degrees of experience.

CONCLUSIONS

Take-home training of basic laparoscopic skills on a mobile box trainer allowed trainees to practice at their own convenience. The increased access to training did not result in trainees passing a test earlier or getting a higher score, but they did engage in shorter and more frequent training sessions. Testing and mandatory training requirements apparently determine training patterns. Trainees could reliably rate their own performance.

CORRESPONDENCE: Ebbe Thinggaard.

E-mail: ebbe.thinggaard@regionh.dk

ACCEPTED: 12 October 2018

CONFLICTS OF INTEREST: Disclosure forms provided by the authors are available with the full text of this article at Ugeskriftet.dk/dmj

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