Coping with complicated situations: mental practice and simulator training to improve performance in adverse situations

Submission date	Recruitment status	Prospectively registered
21/10/2011	No longer recruiting	[] Protocol
Registration date	Overall study status	Statistical analysis plan
16/01/2012	Completed	[_] Results
Last Edited	Condition category	Individual participant data
08/03/2017	Mental and Behavioural Disorders	[] Record updated in last year

Plain English summary of protocol

Background and study aims

All surgical procedures require practice. Learning curves have been described for a variety of operations. In order to increase patient safety, changes in the approach to training surgeons have been suggested and in part implemented. Today the possibility of training outside the operating room in simulation facilities exists. Similar to systems used in aviation, surgeons can practice operations with the help of operation 'simulators'. Unfortunately, the availability of these simulation facilities remains low due to the high costs associated with the equipment. As a response, 'mental practice', a novel method for skills training has been investigated as an addition to training outside of the operating room. Mental practice is the mental rehearsal of a task without actual physical movement. It has been shown to improve performance in motor skill in many different fields such as music and sports. It has also been shown to improve the performance of surgeons in the operating room for simple operations. Apart from technical skill improvement, it has been shown that using mental practice reduces stress levels experienced by junior surgeons. Stress is known to have negative effects on memory, communication and concentration which can lead to medical errors and increase the risk for the patient. Therefore, training aimed at reducing stress for the surgeon has the potential to increase patient safety.

Who can participate? Surgical trainees (junior doctors).

What does the study involve?

Participants are allocated to one of two groups. Those in the first group undergo surgical training using lectures, expert seminars and videos. Those in the second group receive additional training using the method of mental practice which they also continue to do independently at home. This involves mentally rehearsing the operation, going through the operation step by step and visualizing the operation. After one week, the skills of each junior surgeon is assessed in the simulation operating room. This allows the surgeons to perform an operation on a simulator dummy and assess their operative skills. Also, a crisis situation is created during the simulation to evaluate how well the trainee performs during this stressful situation. Furthermore, the overall stress levels of the individual surgeon experiences during the simulated operation as

well as how well the surgeon can communicate with the operating room team during the crisis situation is evaluated.

What are the possible benefits and risks of participating?

All participants receive an additional teaching session regarding the procedure to be performed. Residents who are randomized to the control group have an opportunity to receive the mental practice training once the study is completed if they wish to do so. Information obtained from this study may benefit resident teaching in the future. By taking part in this study there are no risks of physical injury or harm. Elevated levels of anxiety may be experienced during the simulation scenario but this will be comparable to what is encountered in real life crisis situations in the medical profession.

Where is the study run from? Allan Waters Family Simulation Centre at St. Michaels Hospital (Canada)

When is the study starting and how long is it expected to run for? December 2011 to June 2012.

Who is funding the study? Allan Waters Family Simulation Centre at St. Michaels Hospital University of Toronto (Canada)

Who is the main contact? Dr Teodor Grantcharov GrantcharovT@smh.ca

Contact information

Type(s) Scientific

Contact name Dr Teodor Grantcharov

Contact details 30 Bond Street Toronto Canada M5B1W8

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Coping with complicated situations: mental practice and simulator training to improve performance in adverse situations: a randomized trial

Study objectives

Mental practice aimed at teaching crucial operative steps of a complex minimally invasive surgical procedure will improve surgical performance and also lead to a decrease in stress levels experienced by the surgeon. This in turn will improve the surgeons ability to maintain a competent level of communication, leadership and decision-making during a critical scenario and which will ultimately result in better team functioning during a crisis scenario.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design Prospective randomized single blinded trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Reducing stress and improving surgical performance

Interventions

The intervention group will be instructed to apply a mental practice protocol for a complex laparoscopic procedure for surgical training, whereas the control group will undergo only conventional surgical education.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Difference in routine surgical performance (OSATS) between the mental imagery trained and untrained residents

Secondary outcome measures

- 1. Baseline surgeon stress levels during the simulation
- 2. Acute stress reaction
- 3. Overall subjective stress level after the simulation
- 4. Differences in Non-Technical Skills (NOTECHS) scores

Overall study start date 01/12/2011

Completion date 01/06/2012

Eligibility

Key inclusion criteria General surgery residents at the post-graduate year (PGY-3) level or above

Participant type(s) Health professional

Age group Adult

Sex Both

Target number of participants 18

Key exclusion criteria

 Participants with systemic illness leading to an alteration of blood pressure or heart rate such as hypertension, diabetes mellitus or affective disorders
Usage of prescription drugs modifying cardiovascular response

Date of first enrolment

01/12/2011

Date of final enrolment 01/06/2012

Locations

Countries of recruitment Canada Study participating centre St. Michael's Hospital 30 Bond Street Toronto Canada M5B1W8

Sponsor information

Organisation Allan Waters Family Patient Simulation Centre (Canada)

Sponsor details c/o Dr Teodor Grantcharov 30 Bond Street Toronto Canada ON M5B1W8

Sponsor type Hospital/treatment centre

Website http://www.stmichaelshospital.com/education/simulation.php

ROR https://ror.org/04skqfp25

Funder(s)

Funder type Hospital/treatment centre

Funder Name Allan Waters Family Simulation Centre (Canada)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration