Do students learn more about physical examination of the shoulder if they attend a blended learning module compared to 'traditional' teaching methods?

Submission date	Recruitment status	[X] Prospectively registered
24/09/2020	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
02/11/2020	Completed	Results
Last Edited	Condition category	Individual participant data
09/09/2024	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

The study aims to create better evidence on the role of activating competency-based didactics in course development of physical examination skills in preclinical students. It will find out whether integrating clinical investigation techniques and professional posture in an activating competency-based training session will lead to a greater increase in student competence compared to traditional teaching methods with lecture and case demonstrations. Competencies in the above-mentioned areas are assessed with an examination in which the student is asked to examine a patient with shoulder problems.

Who can participate?

All students of the preclinical semesters who are enrolled at the Medical Faculty of Tübingen University

What does the study involve?

Participants will be randomly allocated to either activating competency-based (intervention group) or traditional teaching curriculum (control group). The activating competency-based intervention comprises a 1.5-hour e-learning module on professional posture and clinical examination as well as the functional anatomy of the shoulder. Next, students in the intervention group attend a 1.5-hour peer learning seminar in which they train examining their peers and give mutual feedback. Participants in the control group will receive a 1.5-hour lecture on shoulder anatomy combined with a patient demonstration by a GP. Next, students in the control group are offered 1.5 hours of free training where shoulder models are available. Participants take an exam after 8 weeks. The exam takes about 25 minutes. Participants are given questionnaires at the start of the study and after the exam. The questionnaires take about 15 minutes to complete.

What are the possible benefits and risks of participating? There is no risk for the participants. A personal benefit for the participants is the learning opportunity (clinical elements for pre-clinicians). In order to compensate for any additional time expenditure, students who have participated in the study and passed the examination may partake in a lottery drawing one iPad in each intervention and control group. Furthermore, all participants will receive two cinema vouchers.

Where is the study run from?
University of Tuebingen at the Tübingen University Hospital (Germany)

When is the study starting and how long is it expected to run for? December 2019 to August 2021

Who is funding the study? Faculty internal ProfilPlus funding University of Tuebingen at the Tübingen University Hospital (Germany)

Who is the main contact?
Dr Roland Koch
roland.koch@med.uni-tuebingen.de

Study website

https://www.medizin.uni-tuebingen.de/de/das-klinikum/einrichtungen/institute/allgemeinmedizin/forschung/aus-und-weiterbildungsforschung/trace-x

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Transfer of anatomical knowledge in the examination situation for pre-clinical medical students (TraceX): a randomized, controlled study comparing face-to-face teaching and blended learning

Acronym

TraceX

Study objectives

Current hypothesis as of 24/03/2021:

Preclinical medical students who have completed an activating competency-based learning unit on professional posture, clinical examination skills and basic anatomical knowledge achieve a higher competency score in a simulated shoulder examination than students who have completed the same amount of time in learning modules following traditional teaching methods.

Previous hypothesis:

Preclinical medical students who have completed a blended learning unit on professional posture, clinical examination skills and basic anatomical knowledge achieve a higher competency score in a simulated shoulder examination than students who have completed the same amount of time in face-to-face learning modules.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Assessed 04/05/2020, the study does not require ethic approval (Ethics Committee of the Medical Faculty, Gartenstraße 47, 72074 Tübingen, Germany; +49 7071 29 77661; ethik. kommission@med.uni-tuebingen.de), ref: 231/202BO1

Study design

Two-armed randomized observer-blinded interventional trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Effect of activating competency-based learning on a complex shoulder examination requiring professional posture, transfer of anatomical knowledge and clinical examination skills

Interventions

Current interventions as of 24/03/2021:

Participants (preclinical medical students) will be randomly assigned to either activating competency-based learning (intervention group) or traditional teaching methods.

The blended learning intervention comprises a 1.5-h e-learning module on professional posture and clinical examination as well as functional anatomy of the shoulder. Next, students in the intervention arm attend a 1.5-h peer learning seminar in which they train examining their peers and give mutual feedback.

Participants in the control arm will receive a 1.5 h lecture on shoulder anatomy combined with a patient demonstration by a GP. Next, students in the control arm are offered 1.5 h of free training where shoulder models are available.

Intervention and control at T2 (T0+6 weeks) run parallel and will last 2 weeks in total. They are followed by a 2-day formative exam at T3 (T0+ 8 weeks). For each participant, the exam takes about 25 minutes. In the exam, the effect of the intervention is measured. Participants are given questionnaires at allocation (T0) and after the exam (T4). The questionnaires take about 15 minutes to complete.

The randomization is provided using an open-source online randomization tool (RANDI).

Previous interventions:

Participants (preclinical medical students) will be randomly assigned to either blended-learning (intervention group) or a face-to-face curriculum.

The blended learning intervention comprises a 1.5-h e-learning module on professional posture and clinical examination as well as functional anatomy of the shoulder. Next, students in the intervention arm attend a 1.5-h peer learning seminar in which they train examining their peers and give mutual feedback.

Participants in the control arm will receive a 1.5 h lecture on shoulder anatomy combined with a patient demonstration by a GP. Next, students in the control arm are offered 1.5 h of free training where shoulder models are available.

Intervention and control at T2 (T0+6 weeks) run parallel and will last 2 weeks in total. They are followed by a 2-day formative exam at T3 (T0+ 8 weeks). For each participant, the exam takes about 25 minutes. In the exam, the effect of the intervention is measured. Participants are given questionnaires at allocation (T0) and after the exam (T4). The questionnaires take about 15 minutes to complete.

The randomization is provided using an open-source online randomization tool (RANDI).

Intervention Type

Behavioural

Primary outcome measure

Competency in professional posture, physical examination and anatomical knowledge measured as a combined score of maximum 45 points in an examination situation with an actor patient at T3 (8 weeks)

Secondary outcome measures

A newly developed and piloted questionnaire measures the following items at T0 and T4 and uses a pseudonym to measure pre-post development in the following domains:

- 1. Self-assessed competency level in the three domains (professional posture, anatomical knowledge and clinical examination skills)
- 2. German inventory on attitudes and assessment of blended learning at T0 and T4
- 3. Perceived stress questionnaire (PSYINDEX) at T0 and T4
- 4. Technology affinity (ATI) at T0 only
- 5. Sociodemographic characteristics at T0 only
- 6. Attitudes to e-learning and ways to improve the experience, assessed using focus groups with participants at T4

Overall study start date

01/12/2019

Completion date

30/08/2021

Eligibility

Key inclusion criteria

All preclinical students aged >18 years enrolled at the Medical Faculty of the University of Tübingen

Participant type(s)

Health professional

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80 (40 per study arm)

Total final enrolment

36

Key exclusion criteria

Health status does not allow participation

Date of first enrolment

03/05/2021

Date of final enrolment

28/05/2021

Locations

Countries of recruitment

Germany

Study participating centre

Tübingen University Hospital

Institut für Allgemeinmedizin und Interprofessionelle Versorgung Medizinische Fakultät VITA Gebäude Osianderstr. 5 Tübingen Germany 72076

Study participating centre Eberhard-Karls University Tübingen

Institute of Clinical Anatomy and Cell Analysis Oesterbergstrasse 3 Tübingen Germany 72074

Sponsor information

Organisation

Universitätsklinikum Tübingen

Sponsor details

Medical Faculty Geissweg 5/1 Tübingen Germany 72076 +49 (0)7071 29 73884

forschung.allgemeinmedizin@med.uni-tuebingen.de

Sponsor type

Hospital/treatment centre

Website

https://www.medizin.uni-tuebingen.de/en/Homepage.html

ROR

https://ror.org/00pjgxh97

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Universitätsklinikum Tübingen

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal on medical education. Aside from the main article, the researchers plan to publish a study protocol and a mixed-methods evaluation of the secondary outcomes.

Intention to publish date

01/01/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to privacy reasons of the participants. It can be made available upon resonable personal request. It will be saved on user-restricted, ISO27001 certified servers at UKT.

IPD sharing plan summary

Not expected to be made available