

## Registry of Efficacy and Effectiveness Studies

### Study Title:

Feasibility and effectiveness of guided self-study on examination and treatment competencies of undergraduate physiotherapy students - a pilot randomized controlled trial

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Titel adapted

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[Review this version.](#)

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### Section I: General Study Information

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**Study Start Date:**

2019-08-31

**Study End Date:**

2019-11-23

**Intervention Start Date:**

2019-10-16

**Timing of entry:**

Prior to implementation of the intervention

**Brief Abstract:**

This randomized-group controlled pilot educational study will assess the feasibility and effectiveness of guided self-study on the learning success of undergraduate physiotherapy students. Fifty physiotherapy students should be allocated into a guided self-study group (GSG) or control group. During the third semester, the GSG will receive three guided self-study sessions of 90 minutes each with supervision from a lecturer.

One week in advance of the guided self-study session, the case and the learning goals are provided to the students electronically. The students will prepare the cases in groups with five to six students. The students will be guided by the tutor during this preparation time. The results of the group works will be presented and reflected during a moderated plenum session (90 minutes).

The primary outcome will be the feasibility of the guided self-study including protocol adherence and quality of the proposed cases. The secondary outcomes will be the grades in the objective structured clinical examination (OSCE) exams and written exams that demonstrate the learning success.

**Keywords:**

higher education, learning success, heutagogy

**Comments:**

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*Section II starts on the next page.*

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## **Section II: Description of Study**

**Type of Intervention:**

Curriculum/Product

**Topic Area of Intervention:**

Postsecondary and Adult Education

**Number of intervention arms:**

1

**Target school level:**

University of Applied Science

**Target school type:**

Urban

**Location of Implementation:**

*International:* Europe

**Further description of location:**

Bern, Switzerland

**Brief Description of Intervention Condition:**

The guided self-study sessions will be offered during the third semester over a period of 5.5 weeks. The patient cases used during the guided self-study sessions will be aligned to the module contents of the curriculum (internal medicine, geriatrics and musculoskeletal disorders). The tutor will be a lecturer from the Physiotherapy study course. The structure of the guided self-study sessions is based on Landwehr and Müller [2] and Rogan [3].

Three guided self-study sessions (duration = 90 minutes) are scheduled for the guided self-study group. The physiotherapy students of the guided self-study group will be informed about the case and learning goals one week prior to the guided self-study session. The students will be guided by the tutor during the one-week preparatory phase. Each group will have the opportunity to make an appointment with the tutor to clarify questions and processes, both on-site at the University and via Skype. During the guided self-study sessions, the groups will present results of their work to the tutors as well as to their peers. The guided self-study session will be concluded with reflection and feedback during a moderated in-class plenary session.

**Brief Description of Comparison Condition:**

The control group will have time for three free self-study sessions (duration = 90 minutes) as was traditionally scheduled in the curriculum of the bachelor's degree course. They will not receive a case to study and they will not receive any tutoring activities.

**Comparison condition:**

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**Comments:**

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## **Section III: Research Questions**

**Confirmatory research questions:**

**Question 1:**

Is this study design feasible?

**Question 2:**

What effect does the guided self-study have on practical skills in undergraduate physiotherapy students compared to undergraduate physiotherapy students not receiving the intervention?

**Question 3:**

What effect does the guided self-study have on theoretical knowledge in undergraduate physiotherapy students compared to undergraduate physiotherapy students not receiving the intervention?

**Exploratory research questions:**

No Questions added yet.

**Comments:**

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**Section IV-A: Study Design (Selection)**

**Study Design:**

Randomized Trial (RT)

**Comments:**

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**Section IV-B: Study Design (Input)**

*Study Design: Input*

**Unit of random assignment of intervention:**

Student

**Assignment within sites or blocks:**

Yes

**Define the sites or blocks:**

Cohort

**Probability of assignment to treatment the same across sites or blocks:**

Yes

**Probability of assignment to treatment:**

.50

**Unit outcome data measured:**

Student

**Intermediate clusters between unit of random assignment and unit of measurement:**

No

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**Comments:**

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***Design Classification***

**Based on the responses above, this study has been classified as:**

RT: Multisite (Blocked)

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**Section V: Sample Characteristics**

**Approximate number of students in the comparison condition within each block (Cohort): 25**

**Approximate number of students in the intervention condition within each block (Cohort): 25**

**Number of blocks (Cohort): 50**

No Yes - Yes - If students do not participate in this study No No

**Comments:**

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**Section VI: Outcomes (Input)**

**Confirmatory question 1: Outcome Measure 1**

**Outcome domain:** Student Outcome Domain - Feasibility: Success criteria such as 1) adherence to the guided self-study program, 2) quality of the cases and 3) acceptability of the guided self-study program.

**Minimum detectable effect size:**

**Outcome measure:** guided self-study adherence

**Scale of outcome measure:** Ordinal

**Normed or state test:** Yes

**Same outcome measure in treatment and comparison groups:** Yes

**Confirmatory question 1: Outcome Measure 2**

**Outcome domain:** Student Outcome Domain - Feasibility: Success criteria such as 1) adherence to the guided self-study program, 2) quality of the cases and 3) acceptability of the guided self-study program.

**Minimum detectable effect size:**

**Outcome measure:** Quality of the cases

**Scale of outcome measure:** Continuous

**Normed or state test:** Yes

**Same outcome measure in treatment and comparison groups:** No

**Please Describe:**

Only the intervention group works with the guided self-study cases

**Confirmatory question 1: Outcome Measure 3**

**Outcome domain:** Student Outcome Domain - Feasibility: Success criteria such as 1) adherence to the guided self-study program, 2) quality of the cases and 3) acceptability of the guided self-study program.

**Minimum detectable effect size:**

**Outcome measure:** Acceptability

**Scale of outcome measure:** Ordinal

**Normed or state test:** Yes

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**Same outcome measure in treatment and comparison groups:** No

**Please Describe:**

The number of missing students during the individual guided self-study sessions will be evaluated in the intervention group.

**Confirmatory question 2: Outcome Measure 1**

**Outcome domain:** Student Outcome Domain - Student Achievement - practical skills

**Minimum detectable effect size:**

**Outcome measure:** Objective structured clinical examination (OSCE)

**Scale of outcome measure:** Ordinal

**Normed or state test:** Yes

**Same outcome measure in treatment and comparison groups:** Yes

**Confirmatory question 3: Outcome Measure 1**

**Outcome domain:** Student Outcome Domain - Student Achievement - theoretical knowledge

**Minimum detectable effect size:**

**Outcome measure:** Multiple choice questionnaires

**Scale of outcome measure:** Ordinal

**Normed or state test:** Yes

**Same outcome measure in treatment and comparison groups:** Yes

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**Section VII: Analysis Plan**

**Baseline data collected prior to start of intervention:**

No

**Covariates you plan to include in the model:**

Student Pretest

**Analytic model:**

In order to calculate effects, the Mann-Whitney U test will be applied to determine differences in the exam results between the two groups after the third semester.

**Plan to handle cases with missing outcome data:**

An intention-to-treat analysis will be performed if students not adhere to the guided self-study protocol

**Planned multiple comparisons adjustment, confirmatory question 1 (Student Outcome Domain):**

No

**Comments:**

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**Section VIII: Additional Information**

**Links:**

No links have been added yet.

**Files:**

No Files have been added yet.

**Comments:**

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