Evaluation of the feasibility, acceptability and potential effectiveness of an educational intervention which aims to improve the keep/refer decisions making abilities of Austrian undergraduate physiotherapy students: A randomised pilot study.

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Abstract

Background/Aims

An ongoing discussion about direct access to physiotherapy for patients with musculoskeletal pain disorders in Austria requires the development of a curriculum that educates physiotherapy students to make autonomous keep/refer decisions and to recognise the presence of serious pathologies.

Methods

This randomised pilot study examined the feasibility, acceptability and potential effectiveness of an educational intervention which aimed to improve the keep/refer decision making competencies of Austrian sixth semester undergraduate physiotherapy students.

Findings

Half of Austrian universities (n=6/12) and 116 final year Austrian undergraduate physiotherapy students took part in the study. All students from the intervention group were

satisfied with the intervention and 77.6% found the intervention beneficial for making keep/refer decisions based on clinical vignettes. 89.7% did not find the intervention too time consuming. A potential effectiveness of the intervention could not be demonstrated.

Conclusions

Future similar studies need to investigate if more teaching hours and/or if different educational methods are capable of improving the keep/refer decision making abilities of Austrian undergraduate physiotherapy students.

Introduction

Musculoskeletal (MSK) pain has become a major health problem and substantial socio-economic burden around the globe (Slater and Briggs 2017). One strategy to cut down the staggering financial pressure on health care systems due to MSK pain disorders is the creation of a direct access system to a wider pool of health professions (e.g. to physiotherapy) without the need for prior medical evaluation and/or referral (Marks et al. 2017). Proponents of direct access to physiotherapy argue that there is an associated decline in waiting times for patients (Ojha et al. 2014), a decrease in the workload for doctors (Leemrijse et al. 2008) and a high level of patients' satisfaction when being examined by a primary care physiotherapist (Samsson and Larsson 2014). The preeminent argument of opponents to a direct access system to physiotherapy is that physiotherapists lack formal training to recognise the presence of serious pathologies which require the attention of a physician (Crout et al. 1998; Deyle 2006; Jette et al. 2006; Leemrijse et al. 2008; Piano et al. 2017).

The physiotherapists' and physiotherapy students' ability to recognise serious pathologies

In recent years, studies have revealed limitations of qualified physiotherapists in the United States (Riddle et al. 2004; Ladeira 2018), Germany (Beyerlein 2010), Switzerland (Nast et al. 2013), Doctor of Physical Therapy (DPT) students in the United States (Vaughn et al. 2011)

and of European final year undergraduate physiotherapy students (Lackenbauer et al. 2018; Klein et al. 2018) to accurately identify serious medical conditions which require immediate medical attention based on clinical vignettes. Results by Lackenbauer et al. (2018) and Klein et al. (2018) however revealed that study participants from the Netherlands were more accurate in identifying serious pathologies which require immediate medical attention based on clinical vignettes as compared to German physiotherapy students (Klein et al. 2018) and to physiotherapy students from nine other European countries (including students from Austria) (Lackenbauer et al. 2018). The ability of Dutch physiotherapy students to recognise the presence of serious pathologies is not without reason as the Dutch professional physiotherapy guidelines clearly demand that physiotherapists know when a referral to another health care professional (e.g. a physician) is required (Lackenbauer et al. 2017; Klein et al. 2018).

Physiotherapy education in a changing practice environment

While some European countries already have direct access to physiotherapy (e.g. Finland, Sweden, the Netherlands, the United Kingdom), there is the desire from other national physiotherapy associations including Germany (Konrad and Geraedts 2018), Belgium (ER-WCPT 2018) and Austria (Sorge 2017) to implement a direct access system to physiotherapy. The discussion about direct access to physiotherapy in Austria has more recently led to amendments in the mandatory learning outcomes within the Austrian undergraduate physiotherapy curriculum (Eckler et al., 2017). In the case of direct access to physiotherapy in Austria, it will be then paramount for new graduates to independently screen patients for the presence of serious pathology which requires medical evaluation and/or treatment (Eckler et al. 2017). These amendments (Eckler et al. 2017) now urgently warrant the development of a curriculum that properly educates Austrian undergraduate physiotherapy students to make accurate clinical decisions as to whether a patient is suitable for physiotherapy (keep) or needs the attention of a physician (refer). However, before being included into the existing Austrian

undergraduate curriculum, educational strategies need to be tested for their ability to teach Austrian physiotherapy students how to make sound keep/refer decisions and, most importantly, to recognise the presence of serious medical conditions.

Educational methods within healthcare education

Although it is acknowledged that a wide range of different educational methods exist, three main teaching methods are commonly discussed within the health care education literature (Srinivasan et al. 2007; Tärnvik 2007; Nelson 2010; Lowe 2011):

- The lecture-based format.
- The case-based method (CBL).
- The problem-based method (PBL).

The lecture-based format includes passive acquisition of information which is then subsequently assessed by the amount of information that has been stored by the student (Lowe 2011). Lowe (2011) criticises that the lecture-based format does not examine whether students are able to put the acquired information into use in the clinical, real world setting or context (Lowe, 2011). As opposed to the lecture-based format, PBL and CBL have been introduced. Both approaches foster good clinical reasoning and decision making competencies within health care and medical education (Nelson 2010). Tärnvik (2007) describes that "PBL stimulates students to explore the knowledge needed to understand a given phenomenon, whereas the case method offers opportunities for familiarization and deepening of knowledge already acquired through lectures and other sources" (Tärnvik 2007, p. 33). Although it is still unclear which teaching method produces the better clinicians (Thistlewhaite et al. 2012), a benefit of CBL over PBL is that CBL is less time consuming and possibly more suitable for less experienced learners (Srinivasan et al. 2007).

Feasibility and pilot studies

The development of complex interventions is suggested to follow the Medical Research Council (MRC) framework for the development and evaluation of randomised controlled trials (RCTs) for complex interventions to improve health (MRC 2000). A special form of complex interventions is educational interventions "targeted on the health professional" (MRC 2000: p. 2). To assess whether a future definitive RCT is feasible, multiple feasibility and pilot studies are expected to be carried out prior to a definitive RCT (MRC 2000). The primary objective(s) of feasibility and pilot studies is to test the workability of a future definitive RCT (Eldridge et al. 2016). A definitive RCT will then eventually primarily assess the efficacy/effectiveness of an intervention (Eldridge et al. 2016).

Study objectives and study design

The feasibility, acceptability and potential effectiveness of a CBL educational intervention to improve the keep/refer decision making abilities and recognition rates of serious pathologies of Austrian undergraduate physiotherapy students has not been assessed.

In order to fill this research gap, a randomised pilot study was carried out. This randomised pilot study was conducted in accordance with the CONSORT 2010 statement extension to randomised pilot and feasibility studies (Eldridge et al. 2016).

Methods

Participants, setting and timescales

The recruitment process started in November 2017 and ended in June 2018. To obtain a homogenous sample, this study targeted final year undergraduate physiotherapy students in Austria. The study was carried out as close as possible to the end of the third (final) year. As directly recruiting the students was not feasible (due to the issue of data protection), the lead author contacted heads of the 12 physiotherapy schools in Austria via telephone and e-mail in autumn 2017. These 12 universities had a total of 469 final year undergraduate physiotherapy students. Seven physiotherapy schools showed a high level of interest in this study. These

seven universities had a total of 310 final year undergraduate physiotherapy students. Subsequently, a date convenient for participating universities was arranged. The implementation of the educational intervention and data collection was conducted between February 2018 and June 2018 at the sites of individual universities in Austria. Whilst participation of the students remained voluntary, the heads of physiotherapy schools were asked to promote the study by distributing an information sheet among the target population several weeks before the execution of the study. Interested students were then asked to show up on the (with individual universities') agreed date. After a brief oral description of the study protocol by the lead author in person, written consent from the students present was obtained. No incentives to participate were provided.

Randomisation

The random allocation procedure was conducted identically at each participating university and was administered and monitored by the lead author: Volunteering students were randomly allocated to the intervention or control group by drawing slips of paper without replacement out of a non-transparent bag. Half of the students were then led into a separate room. Students from both groups were only then told which group they had been assigned to. The separate room was necessary to separate the control from the intervention group. This separation was crucial so that students from the control group could not take part in the educational intervention which was exclusively provided to students from the intervention group.

Intervention

The description of the educational intervention followed (where applicable) the guideline for reporting evidence-based practice educational interventions and teaching (GREET) (Phillips et al 2016). The educational intervention consisted of a single, one hour face-to-face CBL lecture on the principles of differential diagnosis, screening for possible red flag pathologies

and review of the body systems (Boissonnault and Bass Part I-III 1990; Henschke et al. 2013; Williams et al. 2013). To avoid any potential errors in the students' understanding as a result of language, the content of all research material was summarized and presented by the lead author in German. The CBL lecture was administered at each participating university exclusively by the lead author who has a six year experience of teaching in a CBL format as a lecturer at a University of Applied Sciences. The control group did not receive an active intervention.

Materials and procedure

To assess the keep/refer decision making competencies of students from both groups, a survey containing 11 validated vignettes (Mount 2012) was used. Clinical vignettes are generally recognised as reliable and valid tools for measuring clinical decision making competencies of health professionals (Peabody et al. 2000; Peabody et al. 2004) and have been widely used in the past to assess clinical decision making competencies of qualified physiotherapists (Riddle et al. 2004; Jette et al. 2006; Beyerlein 2010; Mount 2012; Nast et al. 2013; Ladeira 2018) and physiotherapy students (Vaughn et al. 2011; Lackenbauer et al. 2018; Klein et al. 2018). Students from the intervention group were asked to complete the 11 vignettes immediately after the educational intervention under the supervision of the lead author. Students from the control group completed the 11 cases immediately following the random allocation process in a separate room under the supervision of an administrator from the university. Only one keep/refer answer option per vignette was possible. In accordance with others (Jette et al. 2006; Beyerlein 2010; Nast et al. 2013; Vaughn et al. 2011; Mount 2012; Lackenbauer et al. 2018; Klein et al. 2018) , individual case contents of the 11 vignettes were classified as:

- Musculoskeletal.
- Medical non-critical.

- Medical critical.

Replicating previously used methodology (Jette et al. 2006; Beyerlein 2010; Vaughn et al. 2011; Mount 2012; Nast et al. 2013; Lackenbauer et al. 2018; Klein et al. 2018), a correct answer for the musculoskeletal cases was to treat the patient without the need for medical referral (keep) or to treat the patient with additional medical check-up (keep and refer). A correct answer for the medical non-critical cases was defined if the student(s) chose to start physiotherapy with additional medical evaluation (keep and refer) or refer the patient without physiotherapeutic management (refer). The sole correct answer for medical critical cases was the decision to send the patient for medical evaluation without physiotherapeutic management (refer).

Also in accordance with previous research (Beyerlein 2010; Lackenbauer et al. 2018), students were given a time limit (14 minutes) to complete the 11 vignettes. A time limit for the completion of the 11 vignettes was set to simulate clinical decisions which are made under time pressure (Veloski et al. 2005). The 14 minutes for the 11 vignettes in the current study were calculated based on previous research by Beyerlein (2010) and Lackenbauer et al. (2018). Beyerlein (2010) and Lackenbauer et al. (2018) gave 15 minutes for the completion of 12 vignettes which equals 75 seconds for each vignette. Replicating these numbers as closely as possible, students from the current study sample were given 14 minutes for the completion of 11 vignettes.

Students from the intervention group were also asked to fill out a supplementary questionnaire following the completion of the 11 clinical vignettes. This questionnaire contained three questions which were used to rate the acceptability of the CBL educational intervention from the perspective of students from the intervention group. Due to the lack of availability of identical survey instruments, this questionnaire was developed as a bespoke instrument for the purposes of this randomised pilot study (Appendix 1). The acceptability of the CBL

educational intervention was assessed by following the theoretical framework of acceptability (TFA) by Sekhon et al. (2017) in terms of affective attitude ('were you generally satisfied with the intervention?'), burden ('do you feel that the intervention was too time consuming?') and perceived effectiveness ('do you personally feel that the additional lecture was helpful for you to make an accurate keep/refer decision based on the 11 vignettes?'). No time limit was set for the completion of the supplementary questionnaire.

Outcomes

The primary outcomes were feasibility, acceptability and potential effectiveness and are listed below:

The feasibility of a future RCT was analysed in terms of absolute recruitment rates for students. A recruitment threshold of at least 74 students was determined to indicate the feasibility of a future definitive RCT in relation to recruitment. This was based on using data from an earlier non-randomised-pilot study (unpublished data) and the results from a cross sectional study among European undergraduate physiotherapy students (including students from Austria) (Lackenbauer et al. 2018). A sample size of 37 students in each group was calculated to have 90% power for a future RCT to detect a difference in correct keep/refer decisions for the medical critical vignettes in means of 20% (mean for the control group: 46%; mean for the intervention group: 66%) assuming that the common standard deviation was 26% using an unpaired t-test with an alpha level of 5% (two-sided).

In line with Diamond et al. (2014), a threshold for acceptability in terms of affective attitude, burden and perceived effectiveness of the educational intervention was set to 75% of the students from the intervention group.

The detection of serious medical pathologies, which require medical evaluation, is a key component of an ongoing discussion about increased practice autonomy for physiotherapists in Austria. The focus of the educational intervention was therefore on teaching students how to recognize the presence of serious medical conditions which require a referral to a physician. Hence, it was assumed that students from the intervention group would make on average more accurate answers for the medical critical cases.

Analytical section

Data analysis was carried out using the Statistical Package for Social Sciences (SPSS) for windows version 22.0.0.2 (IBM, USA).

Recruitment rates were analysed using raw counts (percentages and numbers) of participating universities and students in relation to the target population.

As questions about the acceptability of the educational intervention were closed-ended items (categorical data), the frequencies of responses were presented in raw counts (percentages and numbers) of the study sample.

Measurements of central tendency (mean and median) and variability (standard deviation and percentiles) of correct responses for musculoskeletal, medical non-critical and medical critical cases for both the control and intervention group were calculated. In addition, percentages of students from both the intervention and control group who made a correct keep/refer decision for 100% of the musculoskeletal, medical non-critical and medical critical cases were also analysed.

Ethical approval

Ethical approval 1390 was obtained from Manchester Metropolitan University Faculty of Health, Psychology and Social Care Ethics Committee. Heads of physiotherapy schools in

Austria were explicitly asked about the need for additional local ethical approval but it was confirmed that ethical approval from the lead author's host institutions of Manchester Metropolitan University and from the University of Central Lancashire was sufficient.

Results

Feasibility

Heads of physiotherapy undergraduate programmes from seven universities in Austria (58.3%) initially agreed to take part in the pilot study and distributed a description of the study protocol among their final year undergraduate physiotherapy students. The final number of six participating Austrian universities represented 50% of all universities in Austria which provide a bachelor degree in physiotherapy. The final study sample consisted of a convenience sample of 116 sixth semester undergraduate physiotherapy students i.e. - 24.7% of the target population.

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Acceptability

All participants from the intervention group (100%) were satisfied with the intervention (affective attitude). 77.6% (n=45) of the participants from the intervention group reported the lecture to be helpful for completing the 11 vignettes (perceived effectiveness). 89.7% (n=52) of participants from the intervention group did not deem the intervention too time consuming (burden).

Potential effectiveness of the CBL educational intervention

All 116 participants (100%) completed the 11 clinical vignettes. Consequently, all 116 surveys were included in the data analysis. Comparison of the mean and median percentages of accurate keep/refer decisions for the musculoskeletal, medical non-critical and medical

critical vignettes revealed minor differences between the intervention and control group. A correct keep/refer decision for the medical critical vignettes was made on average in slightly more than half of the cases by both groups. Very few participants from both groups managed to make an accurate keep/refer decision for all four vignettes from the medical critical category.

Table 1 and 2 should be inserted approximately here.

Discussion

This was the first study to examine the feasibility, acceptability and potential effectiveness of a one hour, CBL educational intervention which aimed to improve the keep/refer decision making competencies of Austrian undergraduate physiotherapy students. Half of Austrian universities (n=6/12) and 116 final year Austrian undergraduate physiotherapy students took part in the study. 100% of students from the intervention group were satisfied with the intervention (affective attitude) and 77.6% reported the intervention to be beneficial for making keep/refer decisions based on clinical vignettes (perceived effectiveness). 89.7% did not find the intervention too time consuming (burden). The potential effectiveness of a single hour CBL educational intervention could however not be demonstrated.

The high level of the students' satisfaction with an educational intervention based on the CBL approach adopted within the current study is in line with previous reports which have also demonstrated a generally positive attitude towards the CBL method in health care education (Nelson 2010).

The importance of qualified physiotherapists and physiotherapy students learning how to independently recognize the presence of serious pathologies has repeatedly been in the focus of a discussion within the Austrian health care system (Sorge 2017). There is an ongoing desire from the Austrian national physiotherapy association to implement a direct access

system to physiotherapy. This has resulted in amendments to learning outcomes for undergraduate physiotherapy studies across Austria (Eckler et al. 2017). In the case of direct access to physiotherapy in Austria, it will be then paramount for new graduates to independently screen patients for the presence of serious pathology which require medical attention. These amendments (Eckler et al. 2017) pose a significant challenge and this was probably a major reason for the high level of interest from Austrian physiotherapy schools and Austrian final year undergraduate physiotherapy students in this randomised pilot study. Due to the fact that the participation rate exceeded the pre-specified minimum of 74 students, the feasibility in terms of recruitment rates of a future RCT is likely.

When working in a direct access setting, it is crucial to recognise the presence of serious pathologies which are not suitable for physiotherapy but require immediate referral for medical evaluation. Hence, another objective of this randomised pilot study was to observe a potential effectiveness of the CBL educational intervention. Yet, the results from this randomised pilot study failed to demonstrate a potential effectiveness of a single hour CBL educational intervention. One reason for the failed potential effectiveness of the CBL educational intervention possibly was due to its duration. Unfortunately, time constraints from the side of Austrian universities and students at the end of semester six dictated that this randomised pilot study had to be conducted with only one lecture per university and without a follow-up period. Yet, a failed potential effectiveness of the current intervention could also potentially relate to the educational method employed. A systematic review by Thistlethwhaite et al. (2012) showed that CBL is widely recognised as an effective teaching method for educating health professionals. In addition, a benefit of CBL over PBL is that CBL is less time consuming and possibly more suitable for less experienced learners (Srinivasan et al. 2007). On the other hand, Thistlethwaite et al. (2012) pointed out that there

is still inconclusive evidence whether CBL is more effective in producing better clinicians than other learning types.

In the end, students from both groups made on average a correct keep/refer decision in about 50% of the cases from the medical critical category (table 1). In addition, only very few students managed to answer all four medical critical cases correctly (table 2). On the other hand, students had a high level of accuracy for vignettes from the musculoskeletal and medical non-critical category (table 1 and 2). Consequently, students within the current study sample did not overestimate but underestimated the possibility of serious pathologies within clinical vignettes. The weakness to identify serious pathologies based on clinical vignettes is in line with previous reports on qualified physiotherapists in the United States (Riddle et al. 2004; Ladeira 2018), Germany (Beyerlein 2010), Switzerland (Nast et al. 2013), Doctor of Physical Therapy (DPT) students in the United States (Vaughn et al. 2011) and on European final year undergraduate physiotherapy students (Lackenbauer et al. 2018; Klein et al. 2018). The inability to recognise the presence of serious pathologies is especially problematic as the preeminent argument of opponents to a direct access system to physiotherapy is that physiotherapists lack formal training to recognise the presence of serious pathologies which require the attention of a physician (Crout et al. 1998 DA general file; Deyle 2006; Jette et al. 2006; Leemrijse et al. 2008; Piano et al. 2017).

Limitations

Due to the lack of funding, the translation of the 11 vignettes into German had to be solely done by the lead author and did not follow the guidelines for the comprehensive process of cross-cultural adaption of self-report measures described by Beaton et al. (2000). Furthermore, as blinding of study participants and research personnel was ultimately infeasible for the current study, performance bias could not be prevented. As only the experimental group received some educational information (intervention), experimental bias

(Hawthorne effect) could not be ruled out (Portney and Watkins 2009). Furthermore, time constraints from the side of Austrian universities and students at the end of semester six caused for this randomised pilot study to be conducted with only one lecture per university and without a follow-up period. Yet, the study protocol (one lecture with subsequent written exam) was still in accordance with previous research by Boissonnault et al. (2006). Another important issue applies to non-response bias. Students from all volunteering universities were given preliminary information about this study. It was therefore likely that only students took part that were generally interested in the topic of this pilot study and also felt comfortable with the completion of clinical vignettes. Some authors have also condemned the uncritical application of clinical vignettes in health care related research (Veloski et al. 2005; Mohan et al. 2014). Veloski et al. (2005) argued that the answers given by clinicians within clinical vignettes may tend to represent rather idealistic responses and not necessarily the most realistic ones (social desirability bias). The issue of social desirability bias has been further substantiated by Mohan et al. (2014). Their results revealed poor correlation between transfer decisions based on hypothetical cases (vignettes) as compared to real trauma patients in an emergency department (Mohan et al. 2014).

Finally, the generally poorer results for the medical critical vignettes (table 1 and 2) might be explained by the fact that only one answer option (refer) was considered correct. On the other hand, two different keep/refer options for the vignettes of the musculoskeletal (keep or keep/refer) and medical non-critical category (keep/refer or refer) were accurate. Whilst this is acknowledged, the possibility of coming across potential medical emergencies justifies a rigorous approach without any other options for the treating physiotherapist (Lackenbauer et al. 2018).

Conclusion

A single-hour CBL educational intervention which aimed to improve the keep/refer decision making abilities of Austrian undergraduate physiotherapy students was found to be feasible and acceptable. A potential effectiveness of the CBL educational intervention could, however, not be demonstrated. Participants from the intervention group did not make on average more accurate keep/refer decisions for the medical critical vignettes than participants from the control group. This pre-specified criterion was therefore not fulfilled. Consequently, the progression towards a definitive RCT with the primary aim to assess the efficacy of this single hour, CBL educational intervention is not recommended. Before the progression towards a definitive RCT can be recommended, future studies need to determine the optimal amount of teaching hours needed to improve the keep/refer decision making competencies and especially the recognitions rates of serious pathologies of undergraduate physiotherapy students in Austria. It remains unclear which teaching methods produce the better clinicians. Consequently, instead of using a control group, future similar studies might compare different teaching approaches or methods, for example lecture-based versus PBL versus CBL.

National physiotherapy associations that seek direct access to physiotherapy in their countries are well advised to put effort into the development of evidence based educational strategies which have been shown to successfully teach students how to make accurate keep/refer decisions and to recognise serious pathologies with precision. Otherwise, the main argument of the opponents to physiotherapists working as primary care clinicians (that physiotherapists are incapable of recognising serious pathologies) cannot be refuted.

Key points:

- It was feasible to recruit sufficient physiotherapy students for a single hour CBL intervention.

- Students from the intervention group found a single hour CBL intervention which aimed to improve the keep/refer decision making abilities acceptable.

- A one hour CBL intervention did not improve the recognition rates of serious pathologies based on clinical vignettes.

- Future similar studies should assess whether greater contact and teaching hours improve the keep/refer decision making skills.

- Future studies could compare different teaching approaches/methods to assess their impact on keep/refer decision making abilities.

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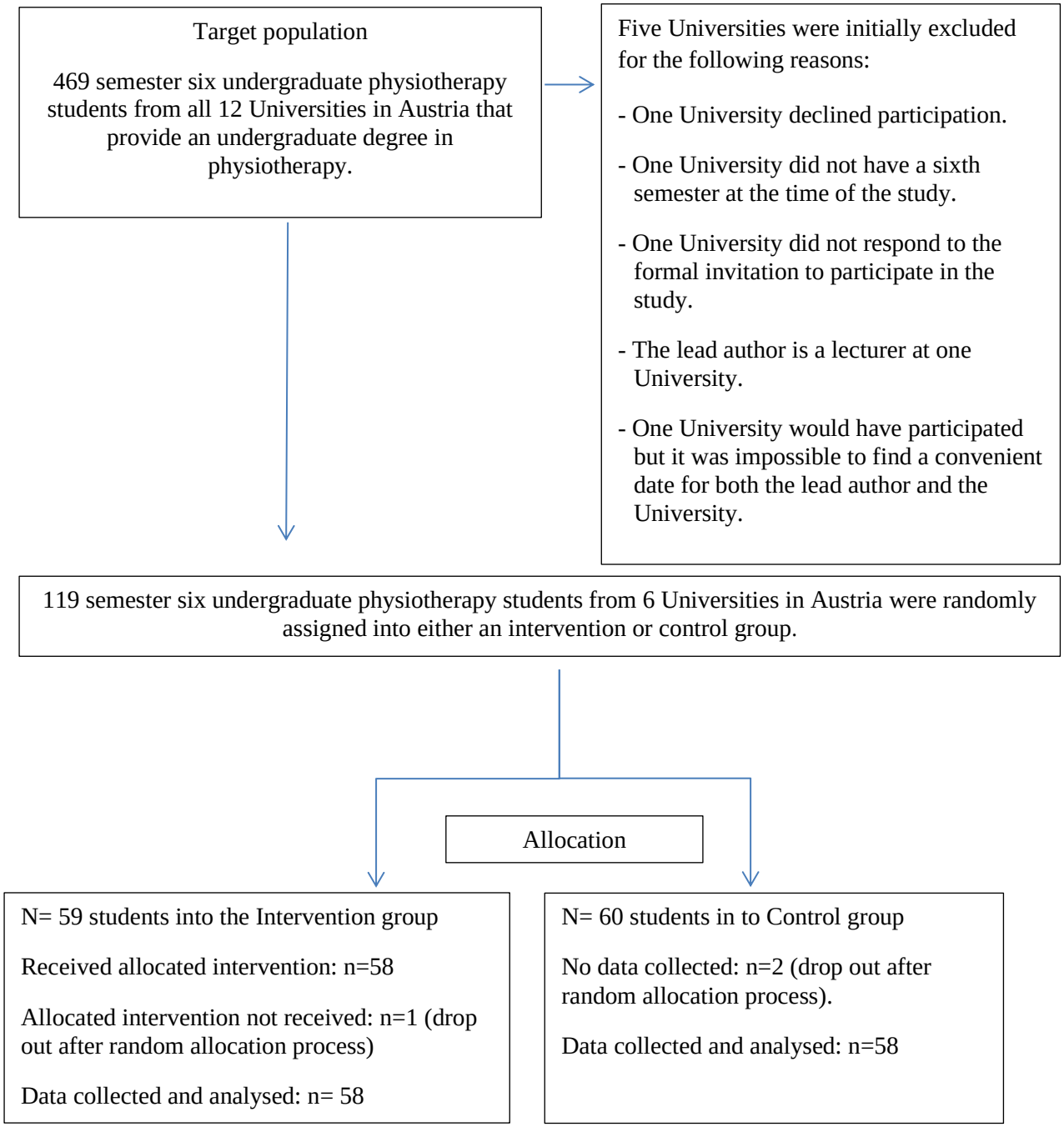

Flow diagram for the randomised pilot study.

Table 1: Mean and median percentages of correct keep/refer decisions for the musculoskeletal, medical non-critical and medical critical vignettes for the intervention and control group.

			Musculoskeletal	Medical non critical	Medical critical
Intervention group	Mean		97.1%	93.5%	52.6%
	Median		100%	100%	50%
	Std. Deviation		9.4%	11.9%	15.3%
	Percentiles	25	100%	93.8%	50%
		75	100%	100%	50%
Control group	Mean		99.4%	88.8%	53.4%
	Median		100%	100%	50%
	Std. Deviation		4.3%	16.9%	21.7%
	Percentiles	25	100%	75%	50%
		75	100%	100%	75%

Table 2: Percentages of participants in each group who made a correct keep/refer decision for all vignettes within each category.

	Musculoskeletal	Medical non critical	Medical critical
	Yes	Yes	Yes
Intervention group	91.4%	75.9%	1.7%
Control group	98.3%	63.8%	3.4%

Appendix 1

Were you generally satisfied with the intervention (lecture)?
Yes ◯
No ◯
Cannot say ◯

Do you personally feel that the additional lecture was helpful for you to make an accurate keep/refer decision (based on the 11 vignettes)?
Yes ◯
No ◯
Unsure ◯

Do you personally feel that the intervention (lecture) was too time consuming?
Yes ◯
No ◯
Cannot say ◯