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"No big deal" – Evaluation of an Obesity Simulation Suit in an Undergraduate Medical Communication Class, a cross-sectional study

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Abstract

Objective:

With the growing prevalence of obesity, medical students should be prepared for communication with this patient group from the early stages of their education onward in order to protect patients from stigmatising experiences and also to reduce prejudices among students.

Design: cross-sectional study

Setting: University Hospital Tuebingen

Participants: N = 246 participants (N = 207 second-year medical students, N = 13 standardized patients and N = 13 teachers) took part in the study.

Primary and Secondary outcome measures: In a simulated role play with a standardised patient (SP) wearing an obesity simulation suit (OSS), students, teachers and SPs filled in questionnaires about the appearance of the OSS and the subscale “weight control/blame” of the Anti-fat Attitudes Test (AFAT).

Results:

The OSS contributed to a more realistic perception of the patient group depicted in a role play according to students, teachers and SP. OSS BMI estimation by students, teachers and SPs correctly was over 30 kg/m^2 – thus in the range of obesity. In a selected subscale of the AFAT, students showed significantly stronger anti-fat stigmatisation compared to teachers and SPs.

Conclusions:

The results of the present study support the need for obesity-specific communication training with medical students, especially in order to prevent stigmatisation and to ensure a high standard of medical care for the target patient group. Based on our data, we conclude that the OSS is a valuable tool for realistically perceived SP encounters.

Article summary

Strengths and limitations of this study:

- Observational investigation of a simulated patient-physician encounter in an undergraduate teaching class.
- Evaluation of an OSS including simulated authenticity, didactic profit and possible difficulties in the perspective of students, SPs and teachers in order to increase degree of fidelity in the simulated situation.
- The study is only in a simulated environment and not with real obese patients

Introduction

Weight issues are a common problem. Over 50 percent of German adults ages 18 to 79 years can be classified as having overweight (BMI ≥ 25.0) and 23% as having obesity (BMI ≥ 30) [1]. Increased weight can cause multiple health problems such as hypertension, type II diabetes, infertility or chronic back pain [2 3]. Both general and abdominal obesity are associated with the risk of premature death, and can affect psychological well-being and self-esteem [4 5]. All these negative implications of high body weight highlight the need for appropriate health care for patients with obesity , particularly as the prevalence of obesity continues to increase [6].

Alongside the health risks related to obesity, stigmatisation plays an important role for patients with overweight or obesity : both conditions are imposed with a socially accepted stigma – when only implicitly measured via gaze behaviour [7], for highly experienced human resource professionals when deciding who to hire for a job [8] and also in the context of public health institutions [8-10]. This stigmatisation makes it more difficult for people with obesity to seek and find help; additionally, it negatively impacts prevention and therapy, thereby imposing implicit and explicit consequences for the health of affected individuals [8 10]. Furthermore, health professionals have been found to communicate in a less patient-oriented and respectful way with obese patients; in particular, they take less time for consultation and explanations, instead attributing patients' problems and symptoms to their weight rather than to disease issues [11]. This seems true not only for the average general physician but also for health professionals from different fields specialised in treatment of obesity such as nursing, physiotherapy, internal medicine or nutrition-coaching [12-18]. With these factors in mind, it appears crucial to sensitise medical students toward the issue of stigmatising patients with obesity by the health work force and to prepare them for appropriate interactions with individuals with obesity. Encounters with SPs can be

seen as an appropriate simulated teaching scenario, offering advantages like availability, possibility to simulate a range of different conversations over time as well as safe exposure to negative events for students and SPs [19 20]. However, it could be shown that aligning the SP's phenotype to the role is critical, as otherwise, the perceived degree of reality might be decreased and thus not considered an authentic learning tool by students [21]. To simulate a highly realistic situation, we designed a scenario with an SP wearing an obesity simulation suit (OSS) in order to authentically simulate a patient with type II diabetes.

Although current literature features broad discussions about the best terminology to describe the tool of an obesity simulating suit ("fat suit" [22], "obesity suit" [23], "simulation suit" [24-26], "weight suit" [27]), we decided to use the term "obesity simulation suit" (OSS) as we consider it the most neutral term in the context of stigmatisation.

To the best of our knowledge, the evaluation of an OSS used in undergraduate medical education has not been used before. In similarly designed studies, the situation has been either students wearing the OSS themselves for self-experience [28] or actual SPs with obesity, which entails the potential danger of issues becoming too personal for the SP [29]. There is also a passionate, ongoing discussion about whether the use of an OSS for self-experience purposes in the context of medical education contributes to decreasing stigmatisation or rather the opposite [22 26 27 30 31]. However, as our intention was to use the OSS as a mean to enhance the degree of fidelity, we want to leave these debates aside for the moment. The OSS was used in the preclinical basic course of the communication curriculum at the Faculty of Medicine at Tuebingen. Students were not expected to experience physical and psychological limitations related to obesity themselves, but rather had to interact with a SP with type II diabetes wearing an OSS. The aim was for these students to develop a more realistic view of the physical and psychological implications of overweight and

obesity, in order to further reflect on their experiences and prejudices in their interactions with patients with obesity and to develop their communication skills. The aim of the present study is to evaluate the influence of an OSS worn by an SP on perceived degree of reality in a doctor-patient simulation. Furthermore, we want to elicit some reflection within the undergraduate medical students on stigmatisation and prejudice against patients with obesity.

Methods

Design

This study presents a cross-sectional design using a quantitative questionnaire survey in a simulated role play as part of a regular longitudinal communication course at the Medical Faculty of Tuebingen. The course has a practical orientation with a focus on students trying out approaches in a safe environment shown to foster the consolidation of professional knowledge and behaviour [32-35]. All second-year medical students from the winter term 2017/2018 and the summer term 2018 were approached. SPs were all from the faculty's SP programme and regularly assigned to the communication course. Teachers were experienced clinicians (physician or psychologist) from the Department of Psychosomatic Medicine and Psychotherapy, and Child and Adolescent Psychiatry, respectively. Participation was voluntary, and all participants gave written consent to take part. The students received no incentive.

Patients and public involvement

No patients or public were involved in this study.

Material

We used an OSS mirroring grade II obesity (BMI 35-39.9kg/m²) from “Perspectives Pioneers” (“PerspektivenPioniere”, Mallersdorf-Pfaffenberg, Bavaria, Germany, see figure 1).

--- figure 1 about here ---

Figure 1. Standardised patient wearing the obesity simulation suit used in the present study to represent a patient with type II diabetes and grade II obesity.

Three different questionnaires for students, teachers and SPs were used. Demographic data were collected from all three groups (gender, age). Teachers evaluated the simulated authenticity and the didactic profit (on a scale ranging from 1 = low to 7 = very high respectively) as well as difficulties related to using the suit (free-text). Students evaluated the simulated authenticity and the degree to which they could empathetically engage in conversation with the SP (on a scale ranging from 1 = low to 7 = very high respectively). Teachers and SPs were asked to specifically select items from a list and report the advantages of the OSS for teaching (teachers) and, accordingly, the difficulties encountered when actually wearing the OSS (SPs). Additionally, SPs evaluated the obesity suit concerning its adequacy for role implementation and its physical burden (on a scale ranging from 1 = low to 7 = very high respectively) as well as possible difficulties (free-text).

Furthermore, a figure rating scale presenting single figures with BMI 18 to 42 [36] and the subscale "weight control/blame" of the Anti-fat Attitudes Test (AFAT) [37] were used and filled in by all participants.

The Anti.-Fat Attitudes Test (AFAT) [37] is a questionnaire comprising 47 items that are scored on a 5-point Likert-type scale (ranging from 1 = strongly disagree to 5 = strongly agree) and was used to assess the negative views of the study participants towards individuals with obesity. The AFAT has three internally consistent factors: "social/character disparagement", "physical/romantic unattractiveness" and "weight control/blame". In regard to dealing with anti-fat attitudes in a medical context, weight control and, accordingly, cognitive attitudes seemed most relevant to us; we decided to use the subscale "weight control/blame". Items of that scale were as follows: 1) There is no excuse for being fat; 2) If fat people really wanted to lose weight, they could; 3) Fat people do not necessarily eat more than other people; 4) Most fat people buy too much junk food; 5) Fat people have no will power; 6) The idea that genetics causes people to be fat is just an excuse; 7) If fat people knew how bad they looked, they would lose weight; 8) Most fat people are lazy; and 9) Most fat people will latch onto almost any excuse for being fat. Cronbach's alpha for this shortened version of the scale was r = .792 representing acceptable reliability for the scale [37].

Procedure

The OSS was worn by SPs presenting as patients with type II diabetes and problems maintaining healthy lifestyle habits. Students as simulated physicians had to take the SP's medical history and explore psychosocial factors related to the diabetes. Teaching took place in small groups of 10 students, one of whom took on the role of

the doctor. Experienced teachers moderated the sessions. Following each session, students, teachers and SPs completed questionnaires anonymously.

To address potential sources of bias we briefed study assistants who were approachable during the survey. Further, we made sure that students could not see the SP without OSS before their physician-patient-encounter.

Data analysis

Mean values (M), standard deviations (SD), frequencies and percentages of relevant factors were calculated. Missing data were replaced by mean. In order to compare the results of the OSS and possible stigmatisation between the different groups, non-parametric tests such as the Mann Whitney U test and Kruskal Wallis test were conducted. The level of significance was $p < .05$. IBM SPSS Statistics version 24 was used for data analysis. Numbers and percentages refer to valid proportions of answers for any given question.

Ethics

Ethical approval for the study was given by the Ethics Committee of Tuebingen's Medical Faculty (No. 683/2017BO2). All participants gave their written informed consent. They did not receive a stipend or other forms of compensation for their participation.

Results

Sample

The sample of *N* = 246 participants (63.8% female) consisted of students (*N*=207, 85.3%), teachers (*N*=22, 9.4%) and SPs (*N*=13, 5.3%) with a mean age of *M* = 24.82 (*SD* = 7.98). All participants took part in the survey. The only reason for non-participation was missing the teaching altogether. For group-specific means, see Table 1.

Table 1.

Demographic data of students, teachers and standardised patients (SP).

	Gender female: male	Age Mean (SD); Range
Students	126:81	22.54 (4.03); 18-55 years
Teachers	18:4	30.43 (5.18); 24-47 years
SP	13:0	51.46 (5.13); 44-56 years

Results of the OSS

In regard to the realistic clinical picture, all three groups reported that the OSS contributes to the realistic appearance of a patient with type II diabetes (M = 5.62 ± 1.19). There was no significant difference in regard to the realism of the scenario between the groups (χ^2 = 2.65; df = 2; p > .05).

Furthermore, the results showed a significant difference in physical strain for the SPs (χ^2 = 12.3; df = 2; p < 0.01). The teachers (M = 4.83 ± 1.23) regarded the physical strain for SPs significantly higher compared to the SPs (M = 3.92 ± 1.08) and to the students (M = 3.82 ± 1.56).

The students tended to agree that the OSS helped them to empathise with the patient who has type II diabetes (M = 4.44 ± 1.61). The teachers evaluated the didactic value added as quite high (M = 5.63 ± 1.41).

Advantages and challenges of the OSS

In free text questions, students, teachers and SPs were first asked about their general remarks about the use of the OSS. Students reported that the look of the OSS impacted them and activated possible stereotypes. For some students, it was difficult to talk about the patient's weight. Students suggested using some of the class time to talk about reservations in regard to people with obesity. In general, most of the students remarked that the OSS made the role play more realistic and aligned with the clinical picture. In free text, teachers supported further use of the OSS in teaching in free text, but criticised the items chosen from the AFAT in the present study as being too negative, one-sided, and stigma-eliciting. They were unsure whether the diabetes case was too difficult for the students who participated in the present study. SPs mainly made specific comments regarding the practicability of the OSS; they first pointed out the importance of matching the clothing style of the SP with the story line of the patient's role and second, they made suggestions about improving clothing (e.g. using stretch trousers instead of jeans with buttons to hasten the change of clothes between role plays).

Among the teachers, 87.0% of the teachers reported that the OSS is authentic. Almost three-fourths of the teachers, 73.9%, thought that the OSS facilitated empathising with the patient in the role play, while 43.5% of them felt that the OSS contributes to making the SP more convincing. In regard to wearing the OSS, 53.8%

of SPs reported that the heat within the OSS was challenging. Furthermore, 23.1% of them stated that its weight and putting it on and taking it off were problematic.

Body impression

Regarding body impression of the OSS, the SPs estimated the BMI of the OSS as highest, with M_{BMI} = 41.25 kg/m^2 ± 1.86 ($p < .001$). The students and teachers evaluated the level of obesity of the OSS correctly as grade II obesity (students: M_{BMI} = 38.00 kg/m^2 ± 3.01; teachers: M_{BMI} = 39.18 kg/m^2 ± 2.90).

The Anti-Fat Attitudes Test and possible stigmatisation

All three groups mostly disagreed with the items of the AFAT when looking at the mean value across all items for all groups (M = 2.18 ± 0.56). Significant differences between groups could be found for five items of the AFAT in particular (for details see table 2). Students were mostly neutral regarding the statement “Fat people could lose weight if they really wanted to”, SPs tended to disagree with this statement the most. Furthermore, the SPs and students tended to agree that “Fat people do not necessarily eat more than others” (variable recoded in table 2). Teachers felt slightly different towards this statement and responded slightly more neutral to it. Regarding the item “Most fat people are lazy” teachers disagreed significantly more to the statement compared to students and SPs. Although there was a significant difference between the three groups for the statements “Most fat people will latch onto almost any excuse for being fat” and “The idea that genetics causes people to be fat is just an excuse”, all three groups tended to disagree or strongly disagree with these statements (mean values for all groups between 1 and 2).

Table 2. Results per group (students, teachers and standardised patients [SP]) for the Anti-fat Attitudes Test (AFAT).

Item AFAT	Group	M	SD	Significance
There is no excuse for being fat.	Students	2.10	± 0.86	χ^2 = 3.37; df = 2; p > .05
	Teachers	1.86	± 0.74	
	SP	1.81	± 0.51	
If fat people really wanted to lose weight, they could.	Students	2.99	± 0.93	χ^2 = 20.76; df = 2; p < .01 **
	Teachers	2.62	± 0.98	
	SP	2.14	± 0.48	
Fat people do not necessarily eat more than other people. (recoded)	Students	2.14	± 1.05	χ^2 = 6.20; df = 2; p < .05 *
	Teachers	2.75	± 1.22	
	SP	2.10	± 0.89	
Most fat people buy too much junk food.	Students	3.07	± 1.03	χ^2 = 3.71; df = 2; p > .05
	Teachers	3.14	± 0.92	
	SP	3.48	± 0.81	
Fat people have no will power.	Students	1.89	± 0.84	χ^2 = 2.39; df = 2; p > .05
	Teachers	2.00	± 1.04	
	SP	1.57	± 0.51	
The idea that genetics causes people to be fat is just an excuse.	Students	1.88	± 0.89	χ^2 = 7.35; df = 2; p < .05 *
	Teachers	1.48	± 0.78	
	SP	2.00	± 0.89	
If fat people knew how bad they looked, they would lose weight.	Students	1.64	± 0.82	χ^2 = 3.74; df = 2; p > .05
	Teachers	1.55	± 0.57	
	SP	1.33	± 0.73	
Most fat people are lazy.	Students	2.47	± 1.01	χ^2 = 7.09; df = 2; p < .05 *
	Teachers	1.97	± 0.68	
	SP	2.35	± 0.59	
Most fat people will latch onto almost any excuse for being fat.	Students	1.94	± 0.92	χ^2 = 8.36; df = 2; p < .05 *
	Teachers	1.48	± 0.74	
	SP	1.62	± 0.50	

** p < .01¸* p < .05

Discussion

In the present study, medical students had to interact with an SP with type II diabetes wearing an OSS with the aim of developing a more realistic view of the physical and psychological implications of overweight and obesity and further reflecting on potential prejudices towards patients with obesity. Based on the results of the present study, the OSS seems to contribute to a more realistic perception of the patient group depicted in a role play of a patient with obesity and type II diabetes according to SPs,

students and teachers. This is for example mirrored in the mean rating when participants were asked how realistic the patient's representation was and also when looking at the data for SPs, students and clinicians in more detail. The physical strain coming along with having to wear an OSS was rated medium by SP, students and teachers. Still, teachers being experienced clinicians rated the physical strain as significantly higher than the other groups, which might possibly be due to the fact that, as an experienced clinician, one may be more aware of the physical strains reported by patients with obesity during daily consultation hours. The BMI estimation by SPs, students and teachers is over 30 kg/m^2 – thus, by definition, in the range of obesity. Still, the BMI estimation was significantly higher in SPs, who were actually wearing the suit, compared to students and experienced clinicians. Therefore, there might be some additional value or gain from actually wearing the suit, as described by Rodriguez et al. [30] and Oldham et al. [38].

Regarding the AFAT, students demonstrated significantly stronger anti-fat prejudices compared to SPs or teachers – underlining the need for specialised teaching modules. Students agreed significantly stronger with the items "Fat people could lose weight if they really wanted to" and "Most fat people are lazy" compared to the two other subgroups of study participants. This is in line with the results reported by Miller et al. [39] who found an implicit anti-fat bias in more than one-third of the medical students in their study – with only a few of them being aware of it.

Students' needs to further reflect on stigmatisation and prejudice against certain patient groups might also be reflected in their desire for a discussion about reservations regarding the patient group in class when answering the free-text field. Specifically regarding the issue of obesity, Miller et al. [39] recommended "Medical schools' obesity curricula should address weight-related biases and their potential

impact on care." They strongly support working on implicit biases with medical students from the early stages of their educations onward.

Further studies should focus on long-term assessments of anti-fat attitudes. In Kushner et al. [29], for example, it could be shown that "in contrast to empathy and counselling, scaled stereotyping mean scores showed a regression back to baseline over a year" – which, to an even greater degree, supports the need for research to focus on variables that support lasting effects of anti-stereotyping interventions. Regarding future research methods on "anti-fat" attitudes, Carl and colleagues [40] suggest the use of a video instrument, which has just been validated within a pilot study.

Moreover, the distinction between explicit and implicit biases should be the focus of attention when working with SPs wearing the OSS, as Sabin et al. [41] found that there is only a weak correlation between explicit and implicit weight bias, thus arguing for these being considered separately. Also, the work of Leehr et al. [7] who observed gaze behaviour in their participants speaks for the necessity of additionally investigating an implicit "anti-obesity" bias.

There are several limitations to the present study. As already reported within the free-text section by SPs, it might be helpful to explicitly choose the clothing style of the patient with obesity according to the role play. However, we do not believe that the perceived degree of reality in the appearance of the patients was influenced by clothing style that did not align perfectly, since in their consideration the realistic aspect of the clinical picture, all three groups (students, teachers and SPs) reported that the OSS contributes to a realistic appearance of a patient with type II diabetes and additionally, 87.0% of the teachers found it authentic and 73.9% thought that the OSS facilitated empathising with the patient in the role play. Moreover, all three

groups realistically estimated the BMI of the SP in the range of obesity by classification.

Furthermore, also referring to the free-text feedback we received, the short version of the AFAT used in the present study was criticised as being “too negative” and its intentions as “too obvious”. We appreciate this feedback and agree to some extent but we want to refer to the original paper by Lewis and colleagues [37] and, accordingly, the subscale’s good reliability and validity. Additionally, our own reliability measure also speaks for an acceptable reliability value of the scale when applied to the sample for the present study.

Despite these limitations, we strongly believe that it seems to be “no big deal” to integrate an OSS into the routine undergraduate medical teaching context with an SP wearing the OSS in an encounter with a medical student, and we see a high potential of this contributing to reducing anti-fat bias in the medical professionals of the future.

Compliance with Ethical Standards

Disclosure of Potential Conflicts of Interest

The authors declared no conflict of interest.

Data sharing

Data are available on reasonable request from the corresponding author.

Ethical Approval

Ethical approval for the study was given by the Ethics Committee of Tuebingen's Medical Faculty (No. 683/2017BO2).

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

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Author contributions

AHW was responsible for the designed and conduction the study, as well as acquisition, analysis and interpretation of data. She drafted the first version of the manuscript. TL and RE were involved in data acquisition, analyses and interpretation and revised the manuscript critically. FJ was responsible for the teaching and revised the manuscript critically. LMW and SZ made substantial contributions to the study design and revised the manuscript critically. All authors approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

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Caption : Caption : Figure 1. Standardised patient wearing the obesity simulation suit used in the present study to represent a patient with type II diabetes and grade II obesity.

57x57mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7-8
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8-9
		(*b*) Describe any methods used to examine subgroups and interactions	8-9
		(*c*) Explain how missing data were addressed	8-9
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	8-9
		(*e*) Describe any sensitivity analyses	N.A.
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	N.A.
		(c) Consider use of a flow diagram	N.A.
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	9-12
Outcome data	15*	Report numbers of outcome events or summary measures	9-12
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-12
		(*b*) Report category boundaries when continuous variables were categorized	N.A.
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N.A.
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	10-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	12-15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14-15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-15
Generalisability	21	Discuss the generalisability (external validity) of the study results	13-14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Is an Obesity Simulation Suit in an Undergraduate Medical Communication Class a valuable teaching tool? A cross-sectional proof of concept study

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Is an Obesity Simulation Suit in an Undergraduate Medical Communication Class a valuable teaching tool? A cross-sectional proof of concept study

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Abstract

Objective:

With the growing prevalence of overweight and obesity, medical students should be prepared to engage in weight management and obesity-related communications in order to prevent patients from stigmatizing experiences. In addition, medical students should have training to reduce anti-fat prejudices.

Design: cross-sectional proof of concept study

Setting: University Hospital Tuebingen

Participants: N = 246 participants (N = 207 second-year medical students, N = 13 standardized patients and N = 13 teachers) took part in the study.

Primary and Secondary outcome measures: the primary outcome is the assessment of degree of reality of the encounter with the SP wearing an obesity simulation suit (OSS). The secondary outcome is the evaluation of students' awareness and prejudice against patients with obesity in a simulated role-play. Additionally, a description of the advantages and disadvantages when using such a teaching tool is delivered.

Results:

The OSS contributed to a realistic perception of the patient group depicted in a role play according to students, teachers and SP. OSS BMI estimation by students, teachers and SPs correctly was over 30 kg/m^2 – thus in the range of obesity. In a

selected subscale of the AFAT, students showed significantly stronger anti-fat stigmatisation compared to teachers and SPs.

Conclusions:

An OSS worn by an SP is a valuable teaching tool to raise awareness for patients with obesity. It gives a realistic picture in the encounter. Stigmatisation was low in general but especially present in the group of students. Further research should include intervention studies to address the issue.

Article summary

Strengths and limitations of this study:

- This study is cross sectional and proof of concept
- Observational investigation of a simulated patient-physician encounter in an undergraduate teaching class.
- Evaluation of an OSS as a teaching tool including simulated authenticity, didactic profit and possible difficulties in the perspective of students, SPs and teachers in order to increase degree of fidelity in the simulated situation.
- The study is only in a simulated environment and not with real patients with obesity

Introduction

Weight issues are a common problem. Over 50% of German adults ages 18 to 79 years can be classified as having overweight (BMI ≥ 25.0) and 23% as having obesity (BMI ≥ 30) [1]. Increased weight can cause multiple health problems such as

hypertension, type II diabetes, infertility or chronic back pain [2 3]. Both general and abdominal obesity are associated with the risk of premature death, and can affect psychological well-being and self-esteem [4 5]. All these negative implications of high body weight highlight the need for appropriate health care for patients with obesity , particularly as the prevalence of obesity continues to increase [6].

Alongside the health risks related to obesity, stigmatisation plays an important role for patients with overweight or obesity [7-9]. Both conditions are imposed with a socially accepted stigma – when only implicitly measured via gaze behaviour [10], for highly experienced human resource professionals when deciding who to hire for a job [9] and also in the context of public health institutions [7-9]. Furthermore, overweight and obesity affect the patient-physician communication and interaction (e.g. doctor shopping or losing trusts in their attending physicians) due to stigmatisation. [11-13] This stigmatisation makes it more difficult for people with obesity to seek and find help; additionally, it negatively impacts prevention and therapy, thereby imposing consequences for the health of affected individuals [8 9]. Furthermore, health professionals have been found to communicate in a less patient-oriented and respectful way with patients with obesity; in particular, they take less time for consultation and explanations, instead attributing patients' problems and symptoms to their weight rather than to other potential causes [14]. This seems not only true for physicians, but also forto health professionals from different fields specialised in treatment of obesity, including nursing, physiotherapy, internal medicine or nutrition-coaching [15-21]. With these factors in mind, it is crucial to make medical students aware of the stigma towards patients with obesity by health care providers and to prepare them for appropriate interactiactions towards this population. . Encounters with SPs can be seen as an appropriate simulated teaching scenario, offering advantages like availability, possibility to simulate a range of different conversations

over time as well as safe exposure to negative events for students and SPs [22 23]. However, it could be shown that aligning the SP's phenotype to the role is critical, as otherwise, the perceived degree of reality might be decreased and thus not considered an authentic learning tool by students [24]. To simulate a highly realistic situation, we designed a scenario with an SP wearing an obesity simulation suit (OSS) in order to authentically simulate a patient with type II diabetes.

Although current literature features broad discussions about the best terminology to describe the tool of an obesity simulating suit ("fat suit" [25], "obesity suit" [26], "simulation suit" [27-29], "weight suit" [30]), we decided to use the term "obesity simulation suit" (OSS) as we consider it the most neutral term in the context of stigmatisation.

To the best of our knowledge, the evaluation of an OSS used in undergraduate medical education has not been used before. In similarly designed studies, the situation has been either students wearing the OSS themselves for self-experience [31] or actual SPs with obesity, which entails the potential danger of issues becoming too personal for the SP [32].

The goals of the study were (1) to assess the degree of reality of the encounter with SP wearing an OSS as a teaching tool (primary outcome) and (2) to evaluate the students' awareness and prejudice against patients with obesity through the encounter (secondary outcome) as well as (3) describe the advantages and disadvantages when using such a teaching tool.

Methods

Design

This study is a cross-sectional, proof of concept study using a quantitative questionnaire survey in a simulated role play as part of a regular longitudinal communication course at the Medical Faculty of Tuebingen. The course has a practical orientation with a focus on students trying out approaches in a safe environment shown to foster the consolidation of professional knowledge and behaviour [33-36]. All second-year medical students from the winter term 2017/2018 and the summer term 2018 were approached. SPs were all from the faculty's SP programme and regularly assigned to the communication course. Teachers were experienced clinicians (physician or psychologist) from the Department of Psychosomatic Medicine and Psychotherapy, and Child and Adolescent Psychiatry, respectively. Participation was voluntary, and all participants gave written consent to take part. The students received no incentive.

Patients and public involvement

No patients or public were involved in this study.

Material

We used an OSS mirroring grade II obesity (BMI 35-39.9kg/m²) from "Perspectives Pioneers" ("PerspektivenPioniere", Mallersdorf-Pfaffenberg, Bavaria, Germany, see figure 1, the individual pictured in the photo gave written consent for the image to be used). The suit consists of two parts: the soft outer shell imitating the typical figure of a patient with obesity and a series of weights worn inside to simulate the additional weight.

--- figure 1 about here ---

Figure 1. Standardised patient wearing the obesity simulation suit used in the present study to represent a patient with type II diabetes and grade II obesity.

Three different questionnaires for students, teachers and SPs were used. Demographic data were collected from all three groups (gender, age). Teachers evaluated the simulated authenticity ("How much does the OSS contribute to a realistic clinical picture?"), the didactic profit (How do you evaluate the didactic profit of the OSS regarding the patient-physician-encounter?") and the physical strain ("How do you estimate the physical strain for SPs?") (all three items ranging from 1 = low to 7 = very high respectively) as well as difficulties related to using the suit (free-text). Students also evaluated the simulated authenticity and physical strain as well as the degree to which they could empathetically engage in conversation with the SP (item ranging from 1 = low to 7 = very high respectively). All items were pre-tested and were seen as reliable with Cronbach's Alpha = .636. Teachers and SPs were asked to specifically select items from a list and report the advantages of the OSS for teaching (teachers) and, accordingly, the difficulties encountered when actually wearing the OSS (SPs). Additionally, SPs evaluated the obesity suit concerning its adequacy for role implementation and its physical burden (items ranging from 1 = low to 7 = very high respectively) as well as possible difficulties (free-text).

Furthermore, a figure rating scale presenting single figures with BMI 18 to 42 [37] and the subscale "weight control/blame" of the Anti-fat Attitudes Test (AFAT) [38] were used and filled in by all participants.

The Anti-Fat Attitudes Test (AFAT) [38] is a questionnaire comprising 47 items that are scored on a 5-point Likert-type scale (ranging from 1 = strongly disagree to 5 = strongly agree) and was used to assess the negative views of the study participants towards individuals with obesity. The AFAT has three internally consistent factors:

"social/character disparagement", "physical/romantic unattractiveness" and "weight control/blame". As weight control and, accordingly, cognitive attitudes were most relevant to us when dealing with anti-fat attitudes in a medical context, we decided to only use the subscale "weight control/blame". Items of that scale were as follows: 1) There is no excuse for being fat; 2) If fat people really wanted to lose weight, they could; 3) Fat people do not necessarily eat more than other people; 4) Most fat people buy too much junk food; 5) Fat people have no will power; 6) The idea that genetics causes people to be fat is just an excuse; 7) If fat people knew how bad they looked, they would lose weight; 8) Most fat people are lazy; and 9) Most fat people will latch onto almost any excuse for being fat. Cronbach's alpha for this shortened version of the scale was r = .792 representing acceptable reliability for the scale [38].

Teaching session

The SP encounter was within the normal basic communication curriculum run by the Department of Psychosomatic Medicine and Psychotherapy. In the proceeding sessions students were familiarised with general communication procedures (e.g. taking a complete medical history, handover of patients, etc.) as well as specific demands of certain situations (e.g. acute case in the emergency department, ward round, communication with patients not speaking German, etc.). The session of the OSS is about the role of life style habits and psychosocial factors in widespread diseases like hypertension or diabetes. The SP presents as a patient with type II diabetes struggling to keep up with self-care (regular exercise, healthy eating, regular intake of medication) coming for a routine follow-up appointment to her GP. Students as simulated physicians had to take the SP's medical history and explore psychosocial factors related to the diabetes. Teaching took place in small groups of

10 students, one of whom took on the role of the doctor. Experienced teachers moderated the sessions. Following each session, students, teachers and SPs completed questionnaires anonymously.

To address potential sources of bias we briefed study assistants who were approachable during the survey. Further, we made sure that students could not see the SP without OSS before their physician-patient-encounter.

Data analysis

Mean values (M), standard deviations (SD), frequencies and percentages of relevant factors were calculated. Missing data were replaced by mean. In order to compare the results of the OSS and possible stigmatisation between the different groups,the non-parametric tests tMann Whitney U test and Kruskal Wallis test were conducted. The level of significance was $p < .05$. IBM SPSS Statistics version 24 was used for data analysis. Numbers and percentages refer to valid proportions of answers for any given question. The qualitative data were evaluated by using context analysis.[39]

Ethics

Ethical approval for the study was given by the Ethics Committee of Tuebingen's Medical Faculty (No. 683/2017BO2). All participants gave their written informed consent. They did not receive a stipend or other forms of compensation for their participation.

Results

Sample

The sample of *N* = 246 participants (63.8% female) consisted of students (*N*=207, 85.3%), teachers (*N*=22, 9.4%) and SPs (*N*=13, 5.3%).. All participants took part in the survey. The only reason for non-participation was missing the teaching altogether. RR of the medical students was 64,7% (207 of 320). For group-specific means, see Table 1.

Table 1.
Demographic data of students, teachers and standardised patients (SP).

	Gender N (%)	Age Mean (SD); Range
Students	207 (60.9)	22.54 (4.03); 18-55 years
Teachers	22 (81.8%)	30.43 (5.18); 24-47 years
SP	13 (100%)	51.46 (5.13); 44-56 years

Results of the OSS

In regard to the realistic clinical picture, all three groups reported that the OSS contributes to the realistic appearance of a patient with type II diabetes (M = 5.62 ± 1.19). There was no significant difference in regard to the realism of the scenario between the groups (χ^2 = 2.65; df = 2; p > .05).

Furthermore, the results showed a significant difference in physical strain for the SPs (χ^2 = 12.3; df = 2; p < 0.01). The teachers (M = 4.83 ± 1.23) regarded the physical strain for SPs significantly higher compared to the SPs (M = 3.92 ± 1.08) and to the students (M = 3.82 ± 1.56).

The students tended to agree that the OSS helped them to empathise with the patient who has type II diabetes (M = 4.44 ± 1.61). The teachers evaluated the didactic value added as quite high (M = 5.63 ± 1.41).

Advantages and challenges of the OSS

In free text questions, students, teachers and SPs were first asked about their general remarks about the use of the OSS. Students reported that the look of the OSS impacted them and activated possible stereotypes. A few students (12 %) reported that it was difficult to talk about the patient's weight. Students suggested using some of the class time to talk about reservations in regard to people with obesity (e.g. missing compassion, disgust, lack of concept of disease) and how to deal with them professionally. In general, most of the students (65%) remarked that the OSS made the role play more realistic and aligned with the clinical picture. In free text, teachers supported further use of the OSS in teaching, but criticised the items chosen from the AFAT in the present study as being too negative, one-sided, and stigma-eliciting. They were unsure whether the diabetes case was too difficult for the students who participated in the present study. SPs mainly (75%) made specific comments regarding the practicability of the OSS; they first pointed out the importance of matching the clothing style of the SP with the story line of the patient's role and second, they made suggestions about improving clothing (e.g. using stretch trousers instead of jeans with buttons to hasten the change of clothes between role plays). Among the teachers, 87.0% reported that the OSS is authentic. Almost three-fourths of the teachers (73.9%) thought that the OSS facilitated empathising with the patient in the role play, while 43.5% of them felt that the OSS contributes to making the SP more convincing. In regard to wearing the OSS, 53.8% of SPs reported that

the heat within the OSS was challenging. Furthermore, 23.1% of them stated that its weight and putting it on and taking it off were problematic.

Body impression

Regarding body impression of the OSS, the SPs estimated the BMI of the OSS as highest, with M_{BMI} = 41.25 kg/m^2 ± 1.86 ($p < .001$). The students and teachers evaluated the level of obesity of the OSS correctly as grade II obesity (students: M_{BMI} = 38.00 kg/m^2 ± 3.01; teachers: M_{BMI} = 39.18 kg/m^2 ± 2.90).

The Anti-Fat Attitudes Test and possible stigmatisation

All three groups mostly disagreed with the items of the AFAT when looking at the mean value across all items for all groups (M = 2.18 ± 0.56). Significant differences between groups could be found for five items of the AFAT in particular (for details see table 2). Students were mostly neutral regarding the statement “Fat people could lose weight if they really wanted to”, SPs tended to disagree with this statement the most. Furthermore, the SPs and students tended to agree that “Fat people do not necessarily eat more than others” (variable recoded in table 2). Teachers felt slightly different towards this statement and responded slightly more neutral to it. Regarding the item “Most fat people are lazy” teachers disagreed significantly more to the statement compared to students and SPs. Although there was a significant difference between the three groups for the statements “Most fat people will latch onto almost any excuse for being fat” and “The idea that genetics causes people to be fat is just an excuse”, all three groups tended to disagree or strongly disagree with these statements (mean values for all groups between 1 and 2).

Table 2. Results per group (students, teachers and standardised patients [SP]) for the Anti-fat Attitudes Test (AFAT).

Item AFAT (1 = strongly disagree to 5 = strongly agree)	**Group**	**M**	**SD**	**Significance**
There is no excuse for being fat.	Students	2.10	± 0.86	$\chi^2 = 3.37$; df = 2; p > .05
	Teachers	1.86	± 0.74	
	SP	1.81	± 0.51	
If fat people really wanted to lose weight, they could.	Students	2.99	± 0.93	$\chi^2 = 20.76$; df = 2; p < .01 **
	Teachers	2.62	± 0.98	
	SP	2.14	± 0.48	
Fat people do not necessarily eat more than other people. (recoded)	Students	2.14	± 1.05	$\chi^2 = 6.20$; df = 2; p < .05 *
	Teachers	2.75	± 1.22	
	SP	2.10	± 0.89	
Most fat people buy too much junk food.	Students	3.07	± 1.03	$\chi^2 = 3.71$; df = 2; p > .05
	Teachers	3.14	± 0.92	
	SP	3.48	± 0.81	
Fat people have no will power.	Students	1.89	± 0.84	$\chi^2 = 2.39$; df = 2; p > .05
	Teachers	2.00	± 1.04	
	SP	1.57	± 0.51	
The idea that genetics causes people to be fat is just an excuse.	Students	1.88	± 0.89	$\chi^2 = 7.35$; df = 2; p < .05 *
	Teachers	1.48	± 0.78	
	SP	2.00	± 0.89	
If fat people knew how bad they looked, they would lose weight.	Students	1.64	± 0.82	$\chi^2 = 3.74$; df = 2; p > .05
	Teachers	1.55	± 0.57	
	SP	1.33	± 0.73	
Most fat people are lazy.	Students	2.47	± 1.01	$\chi^2 = 7.09$; df = 2; p < .05 *
	Teachers	1.97	± 0.68	
	SP	2.35	± 0.59	
Most fat people will latch onto almost any excuse for being fat.	Students	1.94	± 0.92	$\chi^2 = 8.36$; df = 2; p < .05 *
	Teachers	1.48	± 0.74	
	SP	1.62	± 0.50	

** p < .01¸* p < .05

Discussion

In the present study, medical students had to interact with an SP with type II diabetes wearing an OSS with the aim of developing a more realistic view of the physical and psychological implications of overweight and obesity and further reflecting on potential prejudices towards patients with obesity. Based on the results of the present study, the OSS contributes to a realistic perception of the patient group depicted in a

role play of a patient with obesity and type II diabetes according to SPs, students and teachers. The physical strain coming along with having to wear an OSS was rated medium by SP, students and teachers. Still, teachers being experienced clinicians rated the physical strain as significantly higher than the other groups, which might possibly be due to the fact that, as an experienced clinician, one may be more aware of the physical strains reported by patients with obesity during daily consultation hours. The BMI estimation by SPs, students and teachers is over 30 kg/m^2 – thus, by definition, in the range of obesity. Interestingly, the BMI estimation was significantly higher in SPs, who were actually wearing the suit, compared to students and experienced clinicians. This shows that for evaluation of such an extraordinary teaching tool like an OSS, taking into account the perspectives of all parties involved gives valuable insight. Besides a better understanding of the application in general, curriculum designers can also use such information for strategic planning (e.g. deciding which actors can bear the physical strain).

Regarding the AFAT, students demonstrated significantly stronger anti-fat prejudices compared to SPs or teachers – underlining the need for specialised teaching modules. Clinicians from various disciplines have also been shown having prejudices towards patients with obesity – even when working with them on a daily basis. [13] In this study, teachers were all experienced clinicians from the Department of Psychosomatic Medicine and Psychotherapy or Child and Adolescent Psychiatry. Similar studies showed that with experience and thus background knowledge of the underlying causes understanding is enhanced and thus prejudices are reduced. [21 40 41] Students, however, agreed significantly stronger with the items “Fat people could lose weight if they really wanted to” and “Most fat people are lazy” compared to the two other subgroups of study participants. This is in line with the results reported by

Miller et al. [42] who found an implicit anti-fat bias in more than one-third of the medical students in their study – with only a few of them being aware of it.

Students' needs to further reflect on stigmatisation and prejudice against certain patient groups might also be reflected in their desire for a discussion about reservations regarding the patient group in class when answering the free-text field.

Specifically regarding the issue of obesity, Miller et al. [42] recommended "Medical schools' obesity curricula should address weight-related biases and their potential impact on care." They strongly support working on implicit biases with medical students from the early stages of their educations onward.

Further studies should focus on long-term assessments of anti-fat attitudes. In Kushner et al. [32], for example, it could be shown that "in contrast to empathy and counselling, scaled stereotyping mean scores showed a regression back to baseline over a year" – which, to an even greater degree, supports the need for research to focus on variables that support lasting effects of anti-stereotyping interventions. Regarding future research methods on "anti-fat" attitudes, Carl and colleagues [43] suggest the use of a video instrument, which has just been validated within a pilot study.

Moreover, the distinction between explicit and implicit biases should be the focus of attention when working with SPs wearing the OSS, as Sabin et al. [44] found that there is only a weak correlation between explicit and implicit weight bias, thus arguing for these being considered separately. Also, the work of Leehr et al. [10] who observed gaze behaviour in their participants speaks for the necessity of additionally investigating an implicit "anti-obesity" bias.

There are several limitations to the present study. A potential limitation of validity could be the fact that only female SP were used and thus gender-specific differences could not be taken into account. However, for the purpose of the study we explicitly

did not want to add a further level of complexity and thus stuck to one gender only. Additionally, the study noted that students do have bias towards patients with obesity and that they do find the OSS realistic for a simulated encounter. However, it is beyond the scope of this study to address the reduction of bias by using an OSS, which would need to be examined in a pre-post test setting.

To guarantee a realistic scenario, a considerate choice of clothing style for the SP wearing the OSS seems to be crucial. Furthermore, the short version of the AFAT used in the present study was criticised as being “too negative” and its intentions as “too obvious” by participants. We agree to some extent but we want to refer to the original paper by Lewis and colleagues [38] and, accordingly, the subscale’s good reliability as also shown in the present study.

Despite these limitations, we strongly believe that integrating an OSS into the routine undergraduate medical teaching context is a valuable tool. It can raise medical students’ awareness for communication encounters with patients with obesity. This has also been successfully shown for other disabilities in the simulated environment with partially even complete curricula for this topic [45-48].

Outlook

As this study established that the OSS contributes to a realistic appearance of patients with obesity, this kind of simulation can be used to more specifically address the issue of stigmatisation. Here, pre-post testing of the AFAT in such a simulated encounter is necessary. Alternatively, SPs with or without OSS or SPs being actually persons with obesity themselves could be compared.

Compliance with Ethical Standards

Disclosure of Potential Conflicts of Interest

The authors declared no conflict of interest.

Data sharing

Data are available upon reasonable request by the corresponding author.

Ethical Approval

Ethical approval for the study was given by the Ethics Committee of Tuebingen's Medical Faculty (No. 683/2017BO2).

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

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Author contributions

AHW was responsible for the designed and conduction the study, as well as acquisition, analysis and interpretation of data. She drafted the first version of the manuscript. TL and RE were involved in data acquisition, analyses and interpretation and revised the manuscript critically. FJ was responsible for the teaching and revised the manuscript critically. LMW and SZ made substantial contributions to the study design and revised the manuscript critically. All authors approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

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Caption : Caption : Figure 1. Standardised patient wearing the obesity simulation suit used in the present study to represent a patient with type II diabetes and grade II obesity.

57x57mm (300 x 300 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2-3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7-8
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8-9
		(*b*) Describe any methods used to examine subgroups and interactions	8-9
		(*c*) Explain how missing data were addressed	8-9
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	8-9
		(*e*) Describe any sensitivity analyses	N.A.
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9
		(b) Give reasons for non-participation at each stage	N.A.
		(c) Consider use of a flow diagram	N.A.
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	9-12
Outcome data	15*	Report numbers of outcome events or summary measures	9-12
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-12
		(*b*) Report category boundaries when continuous variables were categorized	N.A.
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N.A.
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	10-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	12-15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14-15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-15
Generalisability	21	Discuss the generalisability (external validity) of the study results	13-14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.