The Use of Students as Participants in a Study of Eating Disorders in a Developing Country

Case Study in the Ethics of Mental Health Research

Douglas Richard Wassenaar, PhD and Nicole Mamotte, MSocSc

Abstract: This article describes the ethical analysis of an eating disorder study in which a university-based researcher in South Africa set out to establish the cross-cultural validity of the Eating Disorders Inventory. The following ethical issues are considered in the analysis: study design, social value, study population, risks and benefits, oversight, informed consent, and posttrial obligations. The ethics analysis is based on an adaptation of the structured framework proposed by Emanuel et al. (The Oxford textbook of clinical research ethics; pp. 123–133, 2008) for ethical research in developing countries. The analysis reveals that research that, on superficial analysis, seems to be low risk and noninterventional can result in adverse psychosocial effects and complexities for research participants and researchers alike. The study underlines the need for special ethics scrutiny of mental health–related research proposals involving students as research participants, especially when conducted by their own teachers.

Key Words: Research ethics, mental health research, eating disorders.

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THE RESEARCH PROJECT

The Eating Disorders Inventory (EDI), first developed and standardized in the United States by Garner et al. (1983), has been widely used to assess the psychological dimensions of eating disorders. Although the EDI is only normed on a US population, it has been widely used in non-US settings, both in “Western” and “non-Western” settings (Marais et al., 2003; Podar and Allik, 2009; Tachikawa et al., 2004; Wassenaar et al., 2000). The EDI comprises 64 questions that are clustered into eight subscales, each of which is believed to reflect core psychological symptoms characterizing patients with anorexia nervosa or bulimia. The EDI subscales are Bulimia, Body Dissatisfaction, Drive for Thinness, Perfectionism, Interoceptive Awareness, Interpersonal Disturb, Ineffectiveness, and Maturity Fears. However, relatively little work has been done to establish its validity in developing country settings. Without establishing its validity, studies using the EDI cannot be sure that the EDI profiles generated in populations outside of the United States can reliably be assumed to correlate with clinical eating disorders, nor can data from studies using the EDI be reliably compared with US studies using the EDI.

Consequently, a university-based researcher in a developing country set out to conduct a study toward establishing the cross-cultural validity of the EDI in her own country, South Africa (some elements of this case are hypothetical: the sample size, the nature of the academic reimbursement, and the recruitment strategy). Several publications (Marais et al., 2003; Szabo and Hollands, 1997; Wassenaar et al., 2000) suggested that eating disorders were becoming increasingly prevalent in young African women, especially those who were in “cultural transition” from traditional rural backgrounds to a more “Western” lifestyle, characterized by access to university education, adoption of Western fashion trends, and relationship ideals. In this context, research and clinical questions arose about whether these young women were psychologically similar to eating-disordered women reported in “Western” studies using the EDI (Hooper and Garner, 1986).

The researcher designed a study that aimed to enroll a large sample of (more than 500) female university students. The study would comprise two components: first, the participants would complete an EDI. Secondly, subsamples of high and low scoring participants would then undergo a detailed clinical interview about eating behaviors and attitudes by a clinician-interviewer who was “blind” with regard to each participant’s EDI scores. The interview was a standardized clinical interview with a special focus on eating, weight, and body image–related issues. The interviewer was a clinician skilled and experienced in assessing and treating young women with eating disorders. The aim of the study was to determine whether high and low EDI scores correlated with the experienced clinician’s ratings of the psychological and behavioral features of eating disorders. This, in turn, would provide preliminary validation data on the use of the EDI in a non-Western population.

The university population from which the sample was recruited was a fair reflection of the local and regional South African population demographics (about 68% black African, 15% white, 15% Indian, and the remainder, “colored”) (Statistics South Africa, 2001).

The sample was recruited through posters on departmental notice boards and by lecturing staff who assisted the researcher. Only young women were asked to volunteer for a study examining eating disorders in a South African university sample. The posters mentioned that an exemption from an undergraduate assignment worth 5% of the course credits would be awarded to those enrolling and completing the research requirements. For this reason, only students currently registered for psychology classes were eligible to enroll. Interested parties were asked to contact the researcher who then arranged a one-hour EDI administration session with each participant. At the start of the interview, each respondent was given an information sheet and a consent administration session with each participant. At the start of the interview, each respondent was given an information sheet and a consent form and was allowed to ask questions before deciding whether to enroll in the study or not. About 15% of participants did not keep their appointments. All participants who kept their appointments agreed to participate in the study. They were all asked to consent to a possible follow-up interview.

Once the interview subcomponent of the study began, many (at least 30% to 40%) interviewees became emotionally distressed when discussing their eating-related thoughts, feelings, and perceptions. The distress most commonly took the form of silent weeping that would become evident as eating-, weight-, and body image–related issues were focused on. The researchers did not anticipate this degree of distress in a nonclinical population and had to make late and urgent arrangements to facilitate referrals to the campus health clinic.
BACKGROUND: EATING DISORDERS IN DEVELOPING COUNTRIES

The past 15 to 20 years have witnessed a growing literature on the prevalence of eating disorders in developing countries, especially in countries regarded as non-Western in which acculturation is believed to be taking place (Makino et al., 2004; Podar and Allik, 2009).

Eating disorders are classified in the DSM-IV as characterized by “severe disturbances in eating behavior” (APA, 1995, p. 553). The best-known eating disorders are bulimia nervosa and anorexia nervosa. These disorders typically manifest in late childhood, adolescence, or early adulthood. They share some psychological symptoms (e.g., “undue influence of body weight or shape on self-evaluation” [APA, 1995, p. 559]), and may include food restriction, purging, and compulsive exercise. The incidence and prevalence are difficult to determine globally, and estimates vary widely. Prevalence rates in Western countries for anorexia nervosa and bulimia nervosa range from 0.1% to 5.7% and from 0.3% to 7.3%, respectively, in women (Makino et al., 2004). Prevalence rates in non-Western countries for anorexia nervosa and bulimia nervosa are estimated to range from 0.002% to 0.9% and from 0.46% to 3.2%, respectively, in female subjects (Makino et al., 2004). Most of the cases are female, making it a uniquely gendered psychological disorder, with only about 10% of cases affecting men (APA, 1995).

ETHICAL ISSUES

The following ethical issues will be discussed in the analysis of this study: study design, social value, study population, risks and benefits, oversight, informed consent, and posttrial obligations. The ethics analysis is based on an adaptation of the structured framework proposed by Emanuel et al. (2008) for ethical research in developing countries (Wassenaar, 2006).

Study Design: Collaborative Partnership

The community in which the research is conducted should be involved in the research endeavor (Emanuel et al., 2008). Getting the community’s approval and input ensures that the research is in line with the community’s interests and needs and helps ensure that the research community receives some benefit and is not exploited (Emanuel et al., 2008). Collaborative partnership requires that community representatives be identified, that community culture and values be respected, and that fair benefits be fairly distributed (Emanuel et al., 2008).

The use of student subject pools is often justified as being an opportunity for students to gain “hands-on” exposure to the research process (Diamond and Reidpath, 1992). Students, however, can only benefit from research participation if they are involved throughout the research process (Gates et al., 1999). Collaborative partnerships should be formed with student participants through which researchers share the responsibility of assessing the importance of the research, planning, and conducting the research and disseminating and implementing the results (Emanuel et al., 2008).

In this case, collaborative partnerships should have been formed with women’s health groups on campus and/or with psychology class representatives. The researchers should have engaged with these groups before the research commenced to explore the degree of support for the study and to elicit possible sensitivities and concerns in advance. The researchers should also have met with these groups once the research was completed to discuss the best way to disseminate study results to participants and other relevant stakeholders. These groups could even have been invited to share the responsibility of disseminating the study results and implementing any interventions based on these results.

Study Design: Scientific Validity

The design, methodology, and data analysis of the study should be rigorous, justifiable, and feasible and should lead to valid answers to the research question (Emanuel et al., 2008). Unreliable and/or invalid methods are unethical because they waste resources, yield invalid and unusable results, and expose participants to risk and inconvenience for no purpose (Emanuel et al., 2008).

Using student subject pools may affect the validity of research findings. Validity may be threatened by the limited sample provided by student subject pools (Diamond and Reidpath, 1992). In the present study, for example, only female students currently enrolled in psychology classes at a single university were eligible for enrolment, which may undermine the generalizability and validity of the findings. Furthermore, Henrich et al. (2010) have recently found that although students may be a convenient, low-cost data pool, they are possibly the least representative population from which generalizations can be made.

Social Value

Research should address questions that are of value to society or particular communities in society. Without social value, research participants are exposed to risks for no reason, and scarce resources are wasted (Emanuel et al., 2008). Researchers should identify who the prospective beneficiaries of the research will be and the value the research will have to each of these prospective beneficiaries (Emanuel et al., 2008). The social value of research can be enhanced by developing strategies, through collaborative partnerships, to disseminate the research results to appropriate stakeholders (Emanuel et al., 2008). In this case, the prevalence of eating disorders in this setting was not known, and the validity of the clinical and research use of the EDI in such settings was also untested, suggesting that the study had potential social value.

However, the social value of research is often compromised when research findings are only disseminated through academic publications that are inaccessible to participants or local stakeholders. In the present study, the social value of the research could be increased by disseminating the findings to the university’s campus health clinic or student counseling center so that they may incorporate the findings into the services they offer to university students. Offering participants information on appropriate services available to them would also increase the social value of the research for participants. The investigators should have planned a local dissemination strategy so that the findings were made available to local stakeholders in an appropriate format.

Study Population

Fair participant selection requires that the objectives of the study are the primary basis for selecting study participants (Emanuel et al., 2008). Research participants should be selected in a way that ensures the scientific validity of the research while minimizing risks to selected participants and maximizing the possibility for collaborative partnership and social value (Emanuel et al., 2008). The vulnerability of the research population should also be considered and specific safeguards should be implemented to protect the participants (Emanuel et al., 2008).

In this study, participants were selected from a university population. Students are an accessible and convenient research population (Scott-Jones, 2000). Their centralized location makes student recruitment quicker and easier and reduces the possibility of loss to follow-up (Bonham and Moreno, 2008). Students are also likely to be more compliant and cooperative than the general population as they are used to being monitored and completing tasks assigned to them (Bonham and Moreno, 2008). However, it could be argued that participant selection in this study was not more convenient sampling because eating disorders are most prevalent in the sex and age band sampled.
The “in-house” recruitment, however, raises concerns about the fairness of participant selection because of subordination dynamics between staff and students.

The students’ ability to exercise free choice may be potentially influenced by the subordination dynamics between staff and students, potentially compromising autonomy (Appelbaum et al., 2009). Students invited to participate in research by their lecturers may feel undue pressure to participate if they believe that failure to volunteer may lead to disapproval, loss of favor, or even a decreased grade (Bonham and Moreno, 2008). This perception may make refusing participation difficult. Students may therefore be considered a vulnerable population (Bonham and Moreno, 2008; Tishler and Bartholomae, 2002). Researchers need to consider the vulnerability of student populations, implement specific safeguards to protect them (Emanuel et al., 2008), and implement a range of alternate appropriate academic evaluation methods to ensure that research participation is one of several ways of earning grade credits. Furthermore, students who do not feel free to refuse participation may agree to participate and then passively opt out by providing inaccurate information, impacting the validity of the findings (Brody et al., 1997).

In mental health research, it is likely that a portion of participants in any nonclinical population may have the mental health problem under study (Surkan et al., 2008). For these participants, participation may be a very sensitive matter. Researchers should inform participants of this possibility during the consent process and attempt to identify participants who may be vulnerable to distress before recruitment. This may be done in a screening process by asking participants a series of key questions during the consent process to ascertain their level of vulnerability. Vulnerable participants should not necessarily be excluded from participation but should be treated with care, and researchers should ensure that they understand that they are free to withdraw from the study if they wish. There is data to suggest that in some studies, participants do not always remember study elements that they have consented to (Abdool Karim et al., 1998; Kilmann et al., 2001; Ndebele, 2010), so they should be reminded of their right to discontinue participation if they experience distress. In addition, research ethics committees (RECs) should ensure that researchers have made previous arrangements for participants to receive appropriate debriefing and referral when necessary.

**Risks and Benefits**

All research should have a favorable risk-benefit ratio; that is, the net risks should be balanced by the potential benefits to individual participants and/or the social value of the study (Emanuel et al., 2008). The risk-benefit ratio can best be balanced by minimizing the risks and maximizing the benefits related directly to the research question (Wassenaar, 2006). Benefits to society are secondary to benefits to participants but are nevertheless an important consideration in determining risk-benefit ratio. Safeguards and contingencies should be put in place to deal with foreseeable harms (Wassenaar, 2006).

In psychological research, the risks and benefits are often less tangible or observable than in biomedical research (Scott et al., 2002). As the eating disorder study reveals, mental health studies are often conducted with nonclinical populations without consideration or formal evaluation of the potential psychological distress that may result from participation (Surkan et al., 2008). Furthermore, ethical guidelines often fail to provide guidance on how to measure the potential impact on human participants (Surkan et al., 2008). Increased awareness of these potential problems has led research ethics committees to request mental health researchers to identify and minimize potential harms to participants and to balance these with the benefits of the research. If emotional distress is a potential harm, researchers must identify who might be particularly vulnerable and develop strategies to minimize this harm during the proposed study (Drucker et al., 2009). Formally screening participants for distress may be appropriate in studies with very sensitive subject matter (c.f., Hawkes et al., 2010).

Potential harms in this case included anxiety, painful self-discoveries, stress, indignation, and secondary traumatization (Kelman, 1982). In this study, participation led to self-reflection and disclosure, which may have reminded participants of unpleasant thoughts, affects, experiences, or events (Surkan et al., 2008) and may have eroded their psychological defenses against feelings of low self-worth caused by underlying eating disorder pathology. The researchers in this case anticipated high and low EDI scorers so they should have formed a care and referral plan for such cases, especially high scorers, when the study was designed. The researchers should also have given consideration to the fact that research on sensitive topics, such as eating disorders, could have led to stigma for those enrolled in the study as well as those in the community in which the study was conducted (Taylor and Johnson, 2007). When conducting research on sensitive topics, research staff should be trained to assess the emotional impact of participation, to identify and support participants who become distressed, and to identify when it is necessary to terminate participation (Jorm et al., 2007).

In this case, neither the study team nor the ethics review committee anticipated the level of distress that the EDI and the clinical interview would elicit, probably because the study population was considered nominally nonclinical and because the procedures on the surface did not exceed standard minimal risk criteria. In terms of procedures to prevent or reduce harms, the researchers should have included participant debriefing or referral to counseling services in the study design. To better balance potential harm against acquiring knowledge and direct benefits, the researchers could have implemented measures of participants’ negative and positive experiences during the debriefing process (Surkan et al., 2008). It is also important to monitor the student participants’ well-being and to examine their perceptions throughout the research process, beginning at recruitment. The monitoring of participants’ well-being during the research allowed the researchers to identify the distress and take appropriate action.

The value of participation to students is often cited as an educational benefit for student research participants as they reportedly “get hands-on” research experience from research participation (Diamond and Reidpath, 1992). Bonham and Moreno (2008), however, argue that justifying research participation on the assumption that the process benefits the participant can conceal risks to individual autonomy and fair selection. This assumption more clearly favors the researchers’ ends and should be carefully explored in previous community consultations. Kimmel (1996) suggests that for students to benefit from research participation, researchers should provide educational debriefing sessions after the research is completed for students to reflect on the process and gain insight into the research purpose, methods, results, and conclusions.

**Oversight: Independent Ethical Review**

To ensure public accountability and to minimize concerns regarding researchers’ conflicts of interest, research should be subjected to independent, competent, and transparent ethical and scientific review through procedures established by law and regulation (Emanuel et al., 2008). Research ethics committees should pay special attention to research using student participants because students are considered a vulnerable population (Bonham and Moreno, 2008; Tishler and Bartholomae, 2002). Research ethics committees should ensure that safeguards are put in place to prevent undue influence for students to participate, to ensure that the research is relevant and of value to the student population, and to ensure that using student subject pools does not threaten the validity of the findings (c.f., Henrich et al., 2010).
In this case, the REC appeared to underestimate the potential for emotional distress and did not advise the research team to do previous stakeholder consultations with the study population or to pilot test the methodology in advance to identify risks and potential harms, or to insist on prepared referral options being set up in advance.

Informed Consent

Informed consent is central to ethical research. Informed consent shows respect for research participants and their autonomy by allowing them to decide whether and how they will participate in the research (Emanuel et al., 2008). Researchers should obtain consent in culturally and linguistically appropriate formats and ensure that participants are free to refuse or withdraw participation (Emanuel et al., 2008). When conducting research on emotionally and socially sensitive topics, such as eating disorders, research participants should be fully informed about all potential risks and harms before participation. Their freedom to withdraw or not answer specific questions should be emphasized, and they should be given the contact details of appropriate support services at the onset. The protective role of informed consent may be undermined if inducements and pressures to participate influence potential participants’ willingness to enroll in research. In this case, the study information sheet attached to the consent form should clearly have described the emotionally sensitive nature of the topic and the planned clinical outcomes of high and low EDI scores.

The use of student subject pools is one of the most common ways in which true voluntary consent to research is threatened (Brody et al., 1997). Academic inducements and pressures may undermine students’ free choice of whether to participate or not (Bonham and Moreno, 2008). This is of particular concern if there are more than minimal risks involved in participation (Emanuel et al., 2008).

Academic Inducements

In the study, students were offered an exemption from an undergraduate assignment worth 5% of the course credits in return for enrolling and completing the research requirements. Some researchers believe that as long as research participation is not a course requirement, students are able to volunteer freely even if it involves extra credit or exemption from academic assignments (Bonham and Moreno, 2008). Others argue that when exemptions from academic assignments are offered in return for research participation, the pressure for students to accept makes participation less than voluntary (Bonham and Moreno, 2008). Offers of exemption from academic assignments may even be considered undue inducements because a written assignment requires further study, that is, more time, effort, and stress, and it may hold less appeal than research participation (Bonham and Moreno, 2008; Kimmel, 1996). As such, students may participate in research despite reservations or discomforts they might experience (Kimmel, 1996). In addition, as in the study, research participation often guarantees the student a certain percentage of course credits, whereas completing the alternative assignment does not because the assignment still has to be graded by the lecturer.

In our view, offering students extra credit or exemptions from academic assignments in return for research participation is acceptable as long as equivalent alternatives to research participation are also offered. Alternatives to research participation could include participation in practical, academically relevant community volunteer work, service learning, attending graduate students’ research presentations, or assisting in a research project in some other way, such as assisting with data entry (Kimmel, 1996). Special attention should, however, be paid to the exact academic credits awarded for participation. If these are high in relation to the burdens of the research procedures, it may create an undue inducement to participate, and risks may be overlooked because of the need to earn extra credits.

Before enrolling in a course, students should be made aware of any requirements for research participation, what it entails, what alternatives are available (Kimmel, 1996; Scott-Jones, 2000), and the procedure for questions and complaints (Sieber, 1999). The American Psychological Association guidelines (2002, in Miller and Kreiner, 2008) state that if research participation is a course requirement, students must be given fair alternative options that are not seen as punitive or less attractive than research participation.

Academic Pressure

In this study, the lecturing staff assisted the researcher with recruitment. An unequal power dynamic exists between students and lecturers because students are subordinates within a hierarchical system (Macklin, 2003). Students invited to participate in research by their lecturers may feel undue pressure to participate (Bonham and Moreno, 2008), may fear appearing uncooperative in front of their lecturers, or may have feelings of obligation to researchers who are concurrently their lecturers (Brody et al., 1997; Miller and Kreiner, 2008). Students may believe that failure to volunteer may lead to disapproval, loss of favor, or even a decreased grade. This perception may make refusing participation difficult. To avoid this scenario, researchers in the study could have requested lecturers to allow research staff to have some time at the end of each class to inform the class about the research instead of getting the lecturers to do so directly. Furthermore, the researchers could ask the lecturers to excuse themselves during the information session.

Financial Incentives

Because students are generally financially constrained, they might be more easily induced than the general population to participate in research that offers financial incentives (Macklin, 2003). It is difficult for RECs and researchers to determine when an inducement becomes an undue inducement, potentially compromising voluntariness, especially where research risks are more than minimal (Emanuel, 2004).

Perceived freedom to withdraw from a study may be limited for student participants and is itself an important research question. Students may perceive that they will lose favor or be penalized by withdrawing (Miller and Kreiner, 2008). For example, students’ freedom to withdraw may be impacted in the study scenario because exemption from the academic assignment is contingent on “enrolling and completing the research requirements.” The participants may be unwilling to withdraw from the study if it means forfeiting their assignment exemption and course credits.

Structured assessment instruments are increasingly used in mental health research to evaluate the participants’ competence to consent to research and to determine the voluntariness of their decision. The MacArthur Competence Assessment Tool for Clinical Research, for example, provides researchers with a structured means of assessing potential participants’ capacity to consent to research (c.f., Appelbaum and Grisso, 2001). The present authors have begun to develop and pilot a measure of voluntariness of consent to research. In addition, the Decision Making Control Instrument is being developed to measure participants’ perception of voluntariness when making decisions to enroll in research (c.f., Miller et al., 2009). Assessment instruments such as these may be particularly useful in efforts to maximize autonomous participation when conducting mental health research with student subject pools.

Posttrial Obligations

Disseminating research results during educational debriefing sessions can help student participants reflect on the research process and learn from the research results and conclusions (Kimmel, 1996).
Disseminating the research results and providing feedback to participants who become distressed during the research may help these participants normalize and contextualize their reaction and experience. In this case, the researchers and the approving REC should have insisted on an appropriate dissemination strategy to the population in question, as well as provided relevant results to local student counseling and health services.

CONCLUSIONS
This study shows that research that, on superficial analysis, seems to be of minimal risk and noninterventional can result in adverse psychosocial effects and complexities for research participants and researchers alike. Pilot studies, previous discussions with the community and advocacy and/or self-help groups while studies are being designed may alert researchers to potential emotional consequences of a study before it is initiated. The case underlines the need for a special ethics scrutiny of mental health–related research proposals involving students as research participants, especially when conducted by their own teachers.

FURTHER READINGS
Voluntary Consent
Consent to research participation is only valid if voluntarily given. For a discussion of the voluntariness of consent to research see the following:


Ethical Guidance
Emanuel et al. (2008) provide a framework of ethical principles that, if considered carefully and applied together, should enhance the ethical standing and the scientific value of research. A discussion of their framework can be found in


Participant Distress
There has been ethical concern that psychiatric research may distress participants and worsen their mental state. For a systematic review of this topic, see


Eating Disorders in Developing Countries
The prevalence of eating disorders is increasing in developing countries, especially in countries regarded as non-Western, in which acculturation is believed to be taking place.

A discussion of this issue can be found in


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DISCLOSURE
The authors declare no conflict of interest.

REFERENCES


