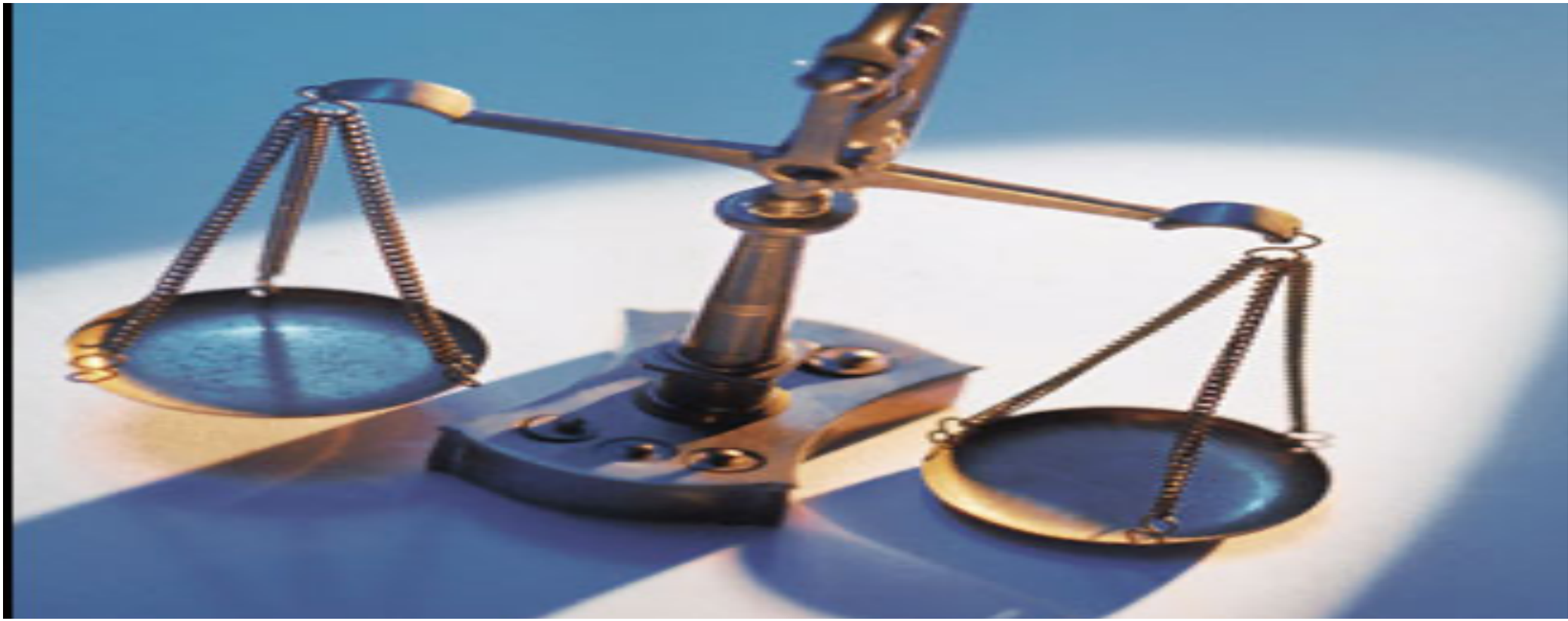


Ethics of research

Research Implications

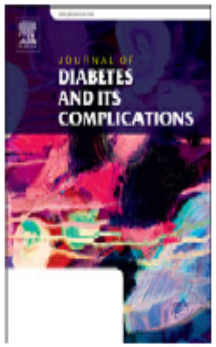
- protocol
- undertaking study
- interpretation
- making recommendations
- presenting your findings

Journal of Diabetes and Its Complications 25 (2011) 247–252

Contents lists available at ScienceDirect

Journal of Diabetes and Its Complications

journal homepage: WWW.JDCJOURNAL.COM



Depression among adults with diabetes in Jordan: risk factors and relationship to blood sugar control☆

Rasmieh M. Al-Amer[a,*], Maha M. Sobeh[b], Ayman A. Zayed[c], Hayder A. Al-domi[d]

[a] Department of Community Nursing, Faculty of Nursing, The University of Jordan, Amman, Jordan
[b] Department of Clinical Nursing, Faculty of Nursing, The University of Jordan, Amman, Jordan
[c] Department of Internal Medicine, Faculty of Medicine, The University of Jordan, Amman, Jordan
[d] Department of Nutrition and Food Technology, Faculty of Agriculture, The University of Jordan, Amman, Jordan

1. Introduction

Diabetes mellitus (DM) prevalence is increasing worldwide, and the World Health Organization (WHO) has described the rising incidence as being of 'epidemic' proportions. Moreover, the WHO predicts that there will be 300 million people having this disease by 2025 (King, Aubert & Herman, 1998; King & Rewers, 1993); as a matter of fact, an increase in the prevalence of type 2 DM is predicted to occur in the Eastern Mediterranean countries and the Middle Eastern ones in particular (King & Rewers, 1993; King et al., 1998), along with the fact that the prevalence of diabetes in the developing countries, such as the Arab countries, varies from 3% in Sudan to 35% in Bahrain (Ajlouni et al., 2008). Considering Jordan, the overall prevalence of DM among adult Jordanians was 17.1, while impaired glucose tolerance was 7.8% in 2002 (Ajlouni et al., 2008). On the other hand, the prevalence of diabetes in the developed countries among adults has been estimated to be about 5% (Linda et al., 2003; Taylor, Keeffe, & World blindness, 2001).

Based on the previously mentioned prevalence of diabetes in different parts of the world and based on the fact that DM is a chronic disease that needs life management by patients, there is an evidence that the risk of depression among diabetic patients is higher than those who do not have diabetes (Anderson et al., 2001; Zahida, Asghara, Claussena, & Huss, 2008), keeping in mind that depression among those with diabetes has been acknowledged to deteriorate and to harm their lives in terms of physical health, functions and quality of life (Brown et al., 2000; Ciechanowski, Katon, & Russo, 2000; Eged, 2004; McCollum, Ellis, Regensteiner, Zhang, & Sullivan, 2007; Rubin & Peyrot, 1999), and it also has been

☆ The University of Jordan provided the funding for this study.

* Corresponding author. PO Box 3678, Amman(11953), Jordan. Tel.: +962 79 6523279; fax: +962 5 3826822.

E-mail address: rasmieh1512@hotmail.com (R.M. Al-Amer).

2. Methods

This study was approved by the University of Jordan in coordination with the Jordan University Hospital's Ethics committee.

2.1. Participants

A systematic random sample (every third patient) of 649 patients was selected from all patients with adult type 1 and type 2 diabetes who attended the Jordan University Hospital over a period of 7 months in 2009 (from July 2009 to January 2010). In a systematic random sampling, a number within the sampling interval was chosen. We chose a random number between 1 and 10 using random number tables; then every third person aged 18 years or above following the first number chosen was selected each day for the whole study period. Participants were informed about the objective of the study. Based on their approval, participants were asked to read carefully and sign a consent form. Bearing in mind the importance of this issue, illiterate patients were given a detailed description of the project.

Patients who are either younger than 18 years or older than 75 years were excluded from the study, along with mentally ill patients (including any patient who was diagnosed of having any kind of depressive disorder, on antidepression medications, or who have

4. Results

4.1. Participant's characteristics

This study included a total of 649 patients (282 male and 367 female) with type 1 and type 2 diabetes aged between 18 and 75 years, with a mean (S.D.) of 57.34 (12.08) years. Most of them had type 2 DM (89.5%), while 10.5% had type 1 DM. Concerning depression, which is the main variable of this study, 19.7% of our sample met the criteria of depression according to the PHQ-8. Their clinical, anthropometric and relevant characteristics are shown in Table 1; 53.2% of our sample had BMI $\geq$30 kg/m^2, 35.9% were illiterate, about 67.7% had duration of DM of <10 years and 88.3% of our participants have hypertension.

4.2. Depression among diabetic patients

Of the 649 patients, 19.7% scored $\geq$10 in the PHQ-8. Depression rate among type 2 diabetes is 20.1% versus 16.2% among type 1 diabetic patients. Table 2 shows the proportion of patients with

5. Discussion

This study estimates the proportion of undiagnosed depression among type 1 and type 2 Jordanian adult diabetic patients and identifies demographic and disease-related risk factors for depression in a large sample of diabetic patients. It also examines the interrelationships of depression, glycemic control, diabetes self-care management and barriers to adherence in patients with type 1 and type 2 DM.

We highly recommend the introduction of the psychological aspect among the diabetic health care plan, to reduce the number of the depressed or the misrecognized depressed diabetic patients and consequently offer them a better quality of life.

Acknowledgments

We thank the patients who participated in this study. We also thank all the doctors and the whole medical staff in the Medical Endocrine Clinic in the Jordan University Hospital for their help during the conduction of the study. We also thank Dr. Azmi Taleb, who shared us the idea of this study, but could not share us the joy of its conduction and completion; unfortunately, he passed away in a tragic road traffic accident, and we all dedicate this article to him. May his soul rest in peace.

References

Ajlouni, K., Khader, Y. S., Batieha, A., et al. (2008). An increase in prevalence of diabetes mellitus in Jordan over 10 years. *Journal of Diabetes and Its Complications*, *22*, 317–324.

American Diabetes Aassociation (2007). Standards of Medical Care in Diabetes — 2007 (position statement). *Diabetes Care*, *30*, S4–S41.

Anderson, R. J., Freedland, K. E., Clouse, R. E., et al. (2001). The prevalence of

ETHICS

- **Greek word: ethos=custom or convention, or the spirit of community**

– moral principles of right and wrong

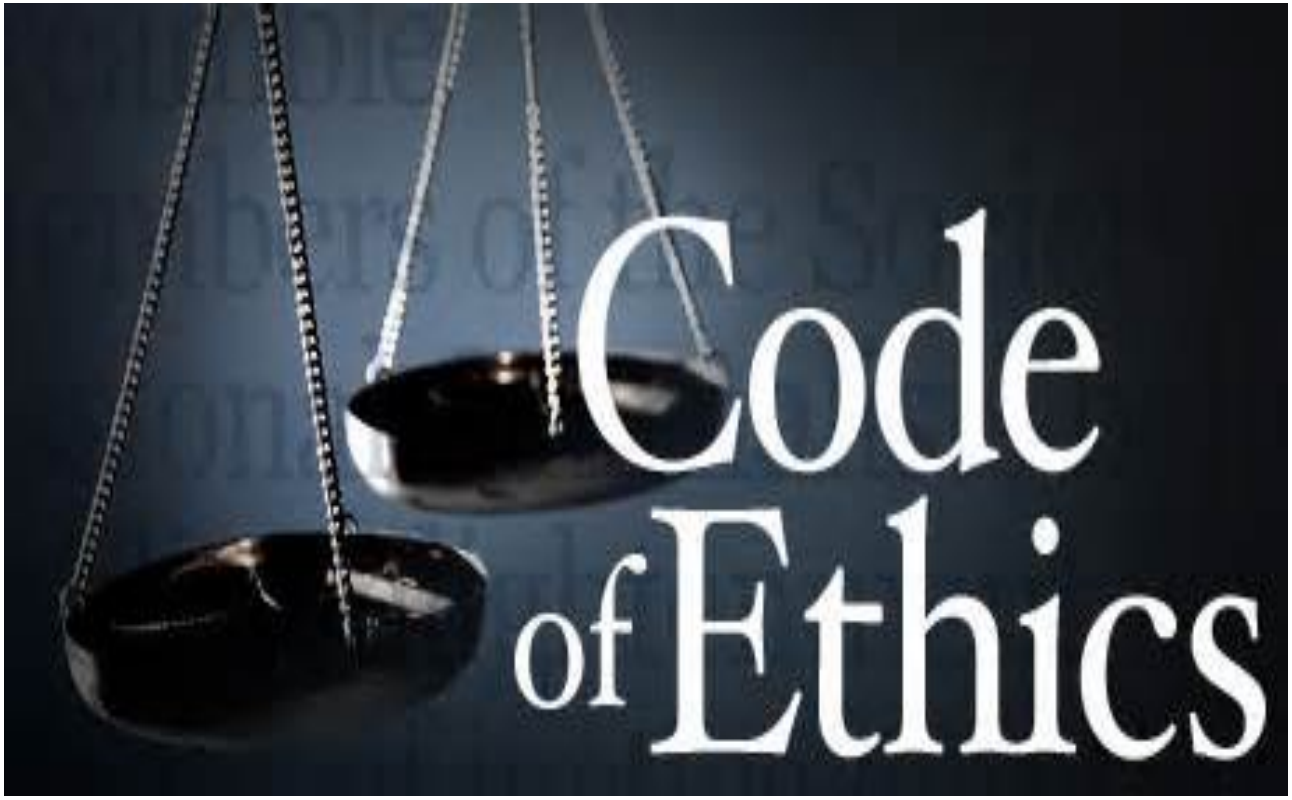
– not absolute; may vary by person, by time, by place

ETHICAL THEORIES

- **Deontology- (deon= duty): duty is the basis of all action**

- **Teleology- (telos = purpose or end): actions can only judged on the basis of consequences they produce.**

HISTORICAL EVENTS AND DEVELOPMENT OF CODE OF ETHICS



1. NAZI MEDICAL EXPERIMENTS (1933-1945)

- **Unethical activities included sterilisation (castration), euthanasia, mutilating surgeries and numerous medical experiments in Nazi concentration camps against prisoners in war.**

- **“Sterilised Jews whom Nazis considered as racial enemies”**

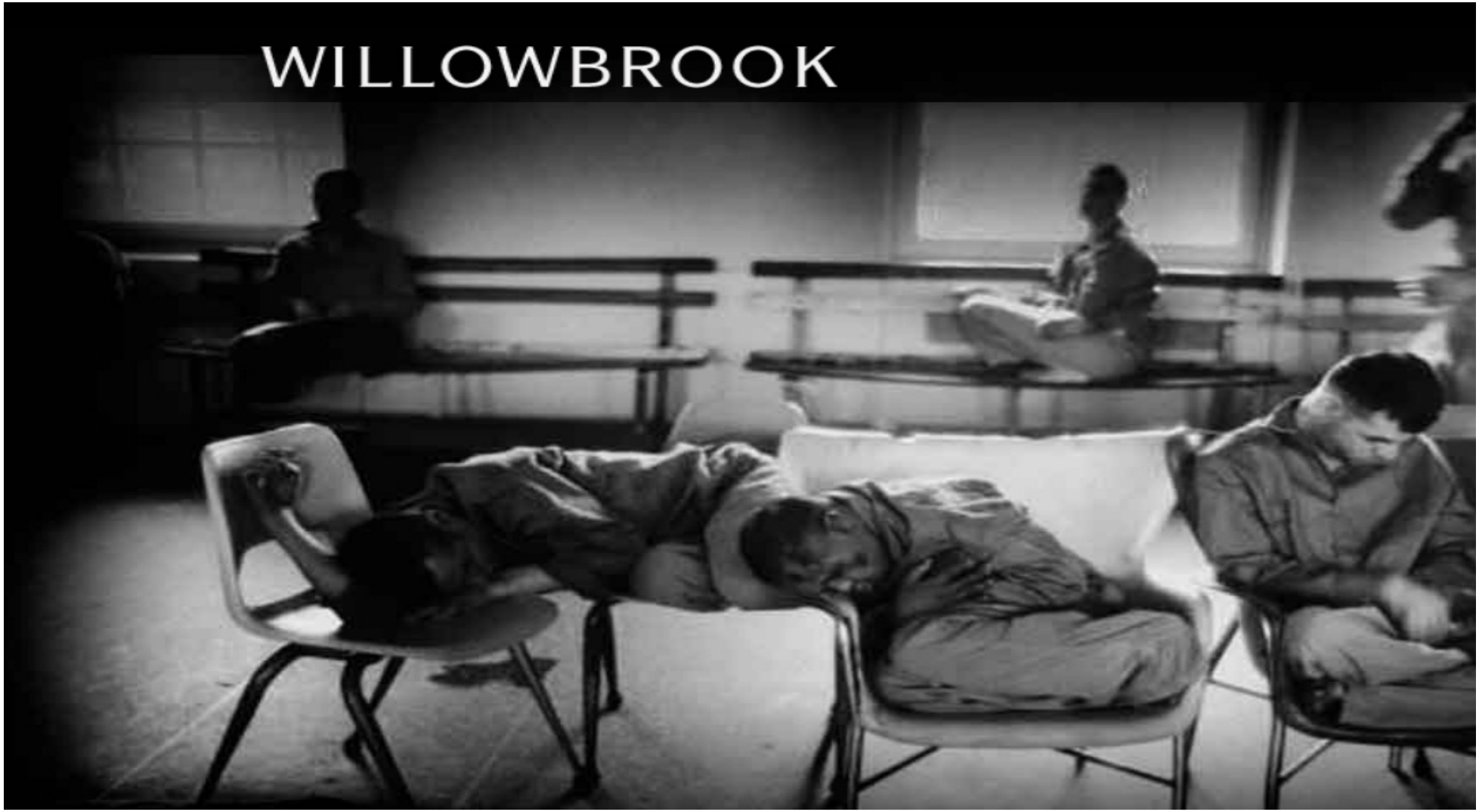
- ***Medical experiments involved exposing to high altitudes, freezing temperature, malaria, poisons, typhus fever, untested drugs and surgery without anaesthesia***
- ***Selection of subjects was racially based***
- ***Subjects had no opportunity to refuse the participation.***

- **Mistreatment of human subjects in Nazi experiments led to the development of Nuremberg Code (1947)**

International code of ethics
NUREMBERG CODE- 1947

- **Nuremberg Code contains 10 guidelines for**
- **Voluntary consent**
- **Withdrawal of subjects from study is possible**
- **Protection of subjects from physical and mental suffering, injury, disability, and death.**
- **The balance of benefits and risks in the study.**

2. WILLOW-BROOK STUDY (1950-1970)



- **Research on hepatitis by Dr. Krugman at Willowbrook among mentally retarded children**
- **Early subjects were fed extracts of stool from infected individuals**
- **Later subjects received injections of purified virus**
- **Parents were forced to give permission for the child to be a subject.**

3. JEWISH CHRONIC DISEASE HOSPITAL STUDY (1960)

- **Study conducted to determine patients' rejection responses to live cancer cells.**
- **Twenty two patients were injected with a suspension containing live cancer cells.**
- **Physician for cancer research directed the study.**
- **Study conducted without the informed consent**

DECLARATION OF HELSINKI (1964)

Was adopted by World Medical association 18th general assembly.

Considered as the standard for medical research ethics.

Revised and updated several times, the last was in 2013.

IMPORTANCE OF ETHICS IN RESEARCH

- **Protects the vulnerable group and other study participants**
- **Participants are safeguarded from exploitation**
- **Establishes risk-benefit ratio for study subjects**
- **Ensures fullest respect, dignity, privacy, disclosure and fair treatment for subject**
- **Builds capability of subjects to accept or reject participation in study at any time.**

INFORMED CONSENT

subjects must be informed fully about the purpose, methods, duration and intended possible uses of the research, what their participation in the research entails and what risks if any, are involved.

Ethical Guidelines for Conduct of Research on Human Subject

- 1. The research is for the good of the society
- 2. Informed consent of the human subject is taken. (voluntariness & transparency)
- 3. The research is based on previous animal study
- 4. The research will not lead to physical or mental suffering.
- 5. There is no risk of disability.
- 6. The risks are minimal in relation to benefit.
- 7. The investigator is scientifically qualified for this research & under supervision. (professional competence)
- 8. The research will be stopped when risk is expected.
- 9. The subject of research could quit the research if he/she suffers any complaints. (compliance)
- 10. Privacy & confidentiality of participants is assured.
- 11. If any harm will occur he/she will be compensated.

Research on human :

- DNA / genomic material: Informed consent for DNA / genomic test and for research will be taken from patients. No further tests will be carried out except with further approval of committee and patients. If the samples will travel outside country the researcher will be responsible for transportation and security approval.

- All drugs used in the research are approved by the Ministry of Health

- Every proposal for medical research on human subjects must be reviewed and approved by an **independent ethics committee** before it can proceed

Journal of Diabetes and Its Complications 25 (2011) 247–252

Contents lists available at ScienceDirect

Journal of Diabetes and Its Complications

journal homepage: WWW.JDCJOURNAL.COM

Depression among adults with diabetes in Jordan: risk factors and relationship to blood sugar control☆

Rasmieh M. Al-Amer[a,*], Maha M. Sobeh[b], Ayman A. Zayed[c], Hayder A. Al-domi[d]

proven that 80% of diabetic patients will experience depression relapses (Lustman, Griffith, & Clouse, 1997); consequently, this will lead to an increase on the health care system's burden, poor glycemic control (Anderson et al., 2001), poor compliance with treatment (Ciechanowski et al., 2000) and increased risk for

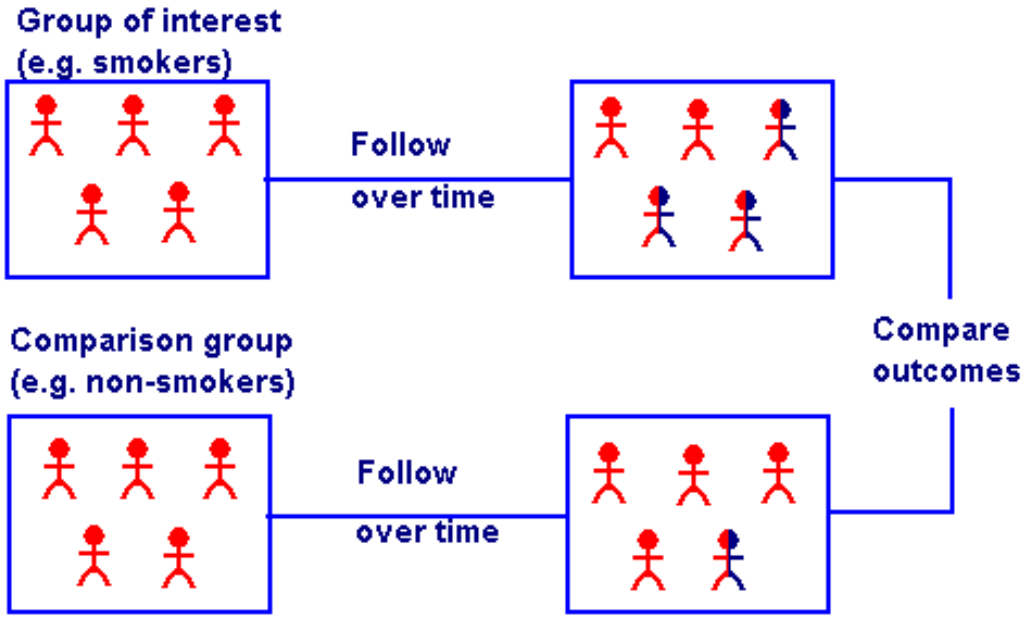
2. Methods

This study was approved by the University of Jordan in coordination with the Jordan University Hospital's Ethics committee.

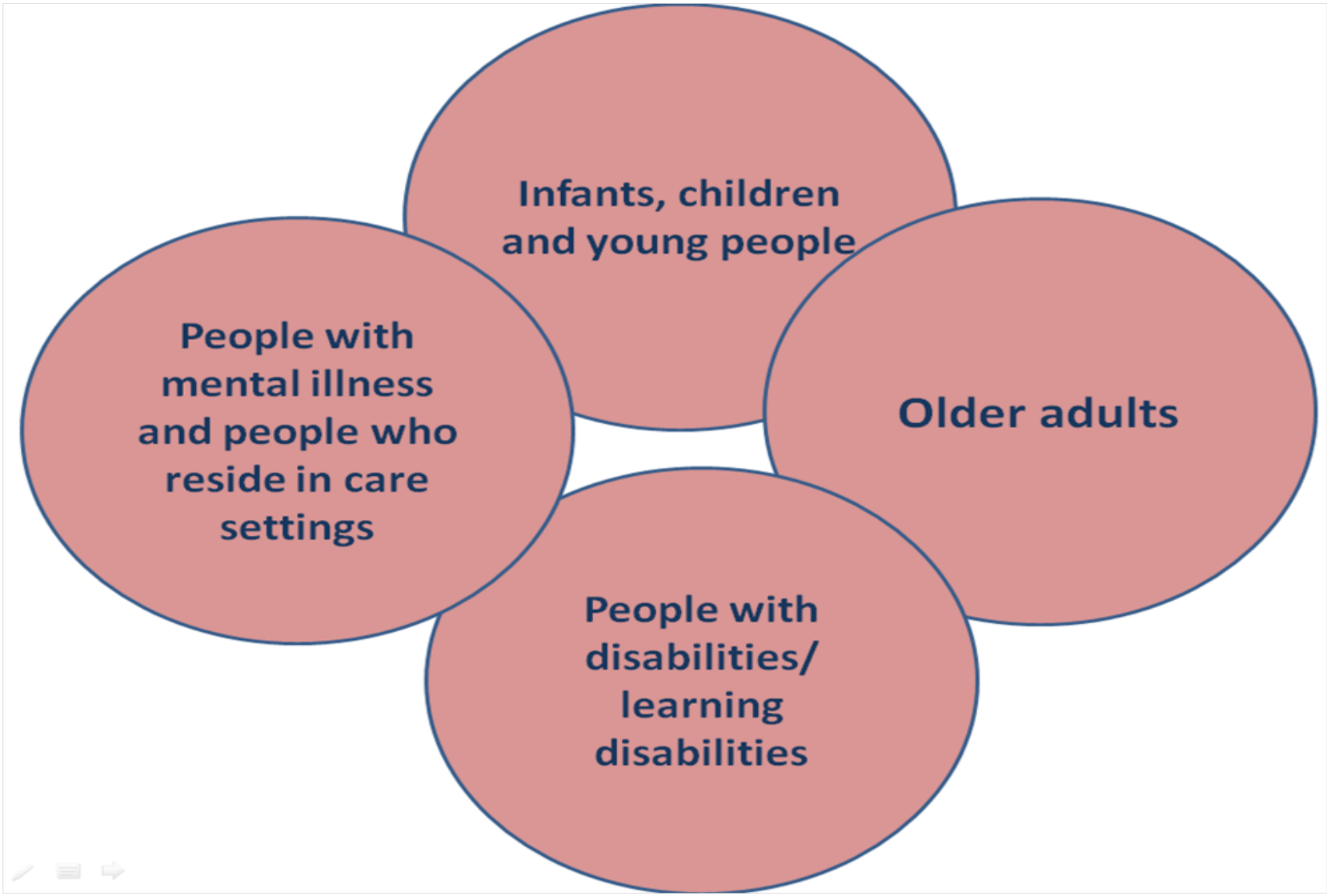
2 types of human experimentations

- **Prospective study:** Informed consent will be taken from patients. In case of incompetent patients the informed consent will be taken from the guardians.

- **Retrospective study:** Confidentiality of records will be considered


Group of interest
(e.g. smokers)
Follow
over time
Comparison group
(e.g. non-smokers)
Follow
over time
Compare
outcomes

VULNERABLE SUBJECTS



Research involving children

Before undertaking research involving children, the investigator must ensure that:

- the research might not equally well be carried out with adults;
- the purpose of the research is to obtain knowledge relevant to the health needs of children;
- a parent or legal representative of each child has given permission;
- the agreement (assent) of each child has been obtained to the extent of the child's capabilities; and, a child's refusal to participate or continue in the research will be respected.

Ethical Guidelines for Conduct of Research on Animals

- A clear scientific purpose is stated.
- The species chosen is satisfactory
- The number of animals will not exceed the requirements of research.
- The process will provide minimal pain & discomfort.
- By the end of experiment the animal will be sacrificed using approved method of euthanasia.
- If there is surgical procedure : anesthesia , antibiotics and postoperative care will be applied.
- The same animal will not be the subject of more than one experiment.
- Disposal of sacrificed animal will be consistent with health and environmental concerns

Areas of Academic misconduct

1. Plagiarism
2. Fabrication and falsification
3. Non-publication of data
4. Faulty data-gathering procedures
5. Poor data storage and retention
6. Misleading authorship

Research misconduct

- *Fabrication is making up data or results and recording or reporting them.*
- *Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or* results.
- *Plagiarism is the use of another person's ideas, processes, results, or words without giving* appropriate credit and presenting them as your own.

PLAGIARISM CHECKER: soft wares

Non-Publication of data

- Sometimes called “cooking data”
- Data not included in results because they don’t support the desired outcome

Data Gathering

- Collecting data from participants who are not complying with requirements of the study
- Using faulty equipment
- Treating participants inappropriately
- Recording data incorrectly
- Most important and most aggravating.

N.B. Store data in a safe and private place for 3 years.

Authorship…

Misleading authorship—who should be an author?

- Technicians do not necessarily become joint authors.
- Authorship should involve only those who contribute directly.
- Discuss authorship before the project!

- Publication of the thesis
  - Should be regarded as the student's work
- Dual publication – a manuscript should only be published in a single journal
- Proper and complete referencing is an essential part of any physics research publication.
- Deliberate omission of an author or reference is unethical and unacceptable.

Ethics of clinical trial & drug development

1. experimentation on animals at first.
2. Follow 4 phases:

- Healthy volunteers (10-80)
- Diseased (100-300)
- Diseased (1000-3000)
- After license and marketing

Ethics of discarded tissue

- Discarded data, documents, records and specimens. (collected for purpose of diagnosis or treatment).

- Informed consent should be taken.

Ethics of stem cell reasearch

- Source: embryo or adult
- Consent of mother for cord blood should be taken
- Consent from couple in spare embryo should be taken
- Should be used in treatment only not for cloning

CONCLUSION

- **Professional codes, laws, regulations, and ethics committees can provide guidance *but ultimate determinant rests with researcher's value system and moral code***


Thank You!