Interactive INTERDEM Academy Seminar: Ethical dilemmas in research practice

Dr. Dorothee Horstkötter
Prof. Dr. Frans Verhey
Dr. Fania Dassen

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Maastricht University

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20-10-2020

Overview of the session

- Introduction to INTERDEM Academy – by Dr Fania Dassen
- Presentation of case examples – by Prof Frans Verhey
- Introduction to research ethics – by Dr Dorothee Horstkötter
- Introduction to research integrity – by Dr Bart Penders (prerecorded presentation)
- Time for discussion and Q&A

INTERDEM Academy

Who?

- Pan-European network of researchers working on psychosocial interventions and early diagnosis of dementia.
- Junior researchers

What?

- Career development
- Training and networking
- Adopting senior roles

INTERDEM
Early detection and timely INTERvention in DEMentia

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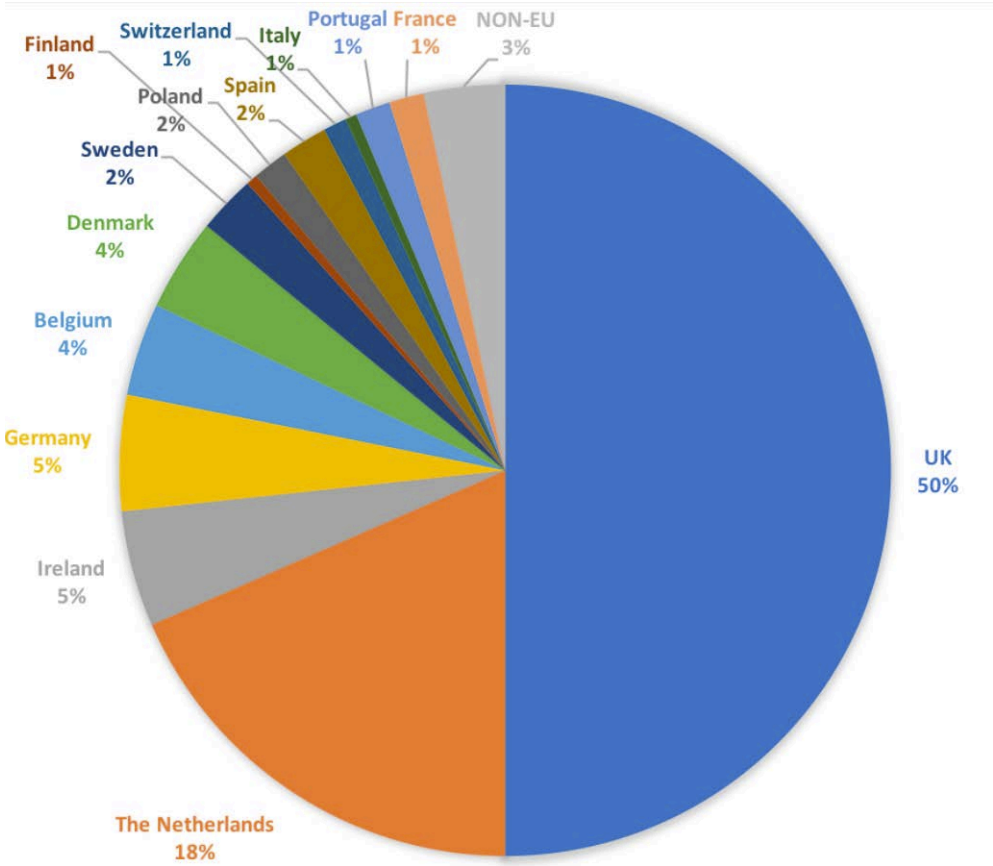
INTERDEM Academy

- Start January 2014
- 200+ early stage researchers
- 66 centers
- 39 countries



Activities

- Masterclasses and summer schools
  - Differential educational programmes:
    - *Early-stage PhD students*
    - *Late-stage PhD students and postdocs*
- Annual INTERDEM session during Alzheimer Europe conference
- 2-day masterclasses in collaboration with DISTINCT:
  - Fifteen Early Stage Researchers (ESRs) across Europe, carrying out research projects aiming to improve the lives of people with dementia and their carers through technology.

dementia: intersectorial strategy for training and innovation network for current technology

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INTERDEM Academy research fellowships

Two fellowships each year
for research exchange

INTERDEM Academy – upcoming activities

- See www.interdem.org
- Continue our training activities (online), travel fellowships postponed
- New: Publication award
- INTERDEM Academy Advisory Board

INTERDEM Academy – become a member

Criteria

- Are you involved in psychosocial research about dementia?
- Do you consider yourself a junior researcher (i.e., PhD student, postdoc) in the field?
- Are you related to or supervised by an INTERDEM member?*

- Send the completed application form (INTERDEM website) to:

Interdem-masterclass@maastrichtuniversity.nl

*We also welcome members who are not affiliated with INTERDEM; they are welcome to be informed about and attend our activities, though they are not eligible for the INTERDEM fellowship.

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Session of today - Today's speakers

Prof Frans Verhey

Dr Dorothee Horstkötter

Dr Bart Penders

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Follow-up session - INTERDEM Academy masterclass

- Dilemma game – please provide us with you name via interdem-masterclass@maastrichtuniversity.nl

https://www.eur.nl/en/about-eur/policy-and-regulations/integrity/research-integrity/dilemma-game

Ethical Dilemma's in Research Practice: three cases

Dorothee Horstkötter

Fania Dassen

Frans Verhey

Case 1 - Peter

- Mr P Is an active and healthy man
- His mother had ‘severe dementia’, was admitted in a nursing home
- He participates in an epidemiological study into risk factors of cognitive aging
- In this study, the Apo-e4 genes profile is being tested, which increases the risk for developing AD
- He now wants to know the results of genetic testing, but in principle, this information will not be shared by researchers as this info has no meaning for individual participants

Case 2 - Gordon

- Mr G is becoming increasingly forgetful, and his wife is really concerned that he might have Alzheimer's.
- He don't want to go to a memory service. He fears that a diagnosis would change his life, practically and in terms of her self-image and relationships.
- His wife wants him to be tested in the university memory center. She hopes that then he might participate in a trial

Case 3 - Carola

- Mrs C is a 72 year old woman diagnosed with Mild Cognitive Impairment, prodromal Alzheimer's disease (positive biomakers)
- Her doctor told her that he can offer psychological support and case management, but, currently, there is no medication
- He mentiones that there is a very promissing drug
- But only in the context of a 18 months RCT (randomized controlled trial), for which he has to refer her to an University Alzheimer Center

Research Ethics: Why? What? How?

20th October 2020, dr Dorothee Horstkötter

Interdem Academy, Alzheimer Europe Conference

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https://www.alzheimer-europe.org/Ethics/Ethical-issues-in-practice/2011-Ethics-of-dementia-research

What is ethics?

What is good? What do we ought to do?

Ethical questions concern **norms and values**

Norms: rules, agreements, guidelines, principles – based on values

Values: The good, the valuable what is worthwhile to be achieved.

Ethical statements **cannot be tested objectively** as true or untrue

Ethical statements **must be justified**. They need reasonable arguments

What is medical ethics?

The ultimate goal of health care: **Help the patient**

Provide for safe and effective treatment

Inform patients about their health condition, prospects and possibilities

Patients take part in decision-making on treatment, have the final say.

Patients judge how well they feel helped

Subject-subject relationship (dialogue)

What is research ethics?

The ultimate goal of health research: **Gain knowledge, help society, future patients.**

Conduct research that has social and scientific relevance

Be methodologically sound, have adequate sample size and perform study in due time

Researchers decide about study set-up, procedures to be followed

Randomization decides in which group a partipant takes part in

Researcher judges whether data are reliable and results are valid

Subject-object relationship (participants are means to data-gathering)

The ethical challenge of the good researcher

Immanuel Kant (1724-1804):

"Never treat people merely
as a means to an end, but always (also) as
ends-in-themselves"

Pure subject-object relationships
are never ethically justifiable.

Jürgen Habermas (1929-)

Subject-object relationships should always be embedded in a subject-subject relationship for being ethically justifiable.

Focus on subject-subject relationships also in health research

What are human beings?

1) Humans give themselves goals and try to achieve these.

2) Humans are psycho-physiological beings and experience pain and pleasure.

3) Humans are social beings and live in social communities.

(Medical) Ethics for human beings: 3 principles

1) Self-determination or autonomy

2) Beneficence and non-maleficence

3) Justice

Research Ethics for human beings: 3 corresponding p

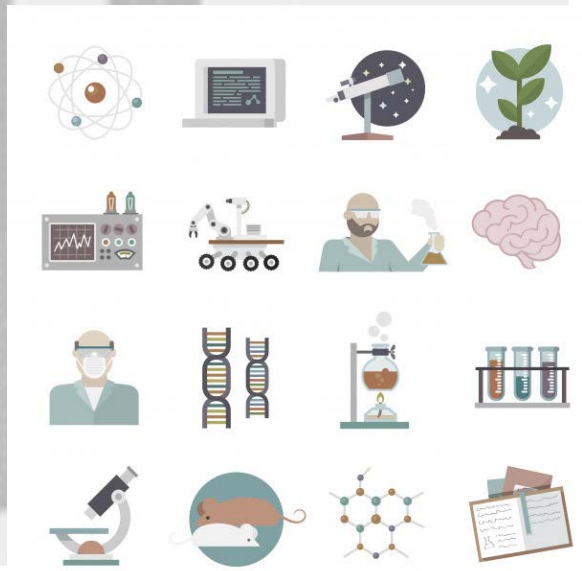
In medical research these three ethical principles can come under pressure.

Three corresponding ethical principles to uphold ethical relationship between researcher and participant.

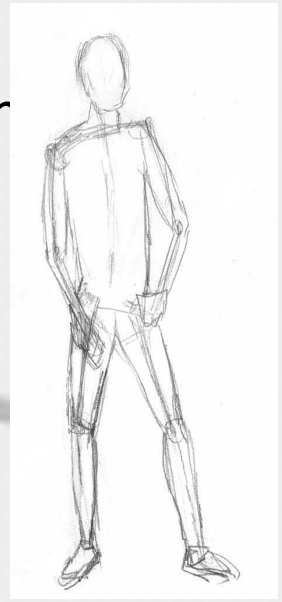
1) Informed consent

2) Proportionality of risk/burden and benefits

3) Fair research participant selection



Research Ethics for human beings: 3 corresponding prir



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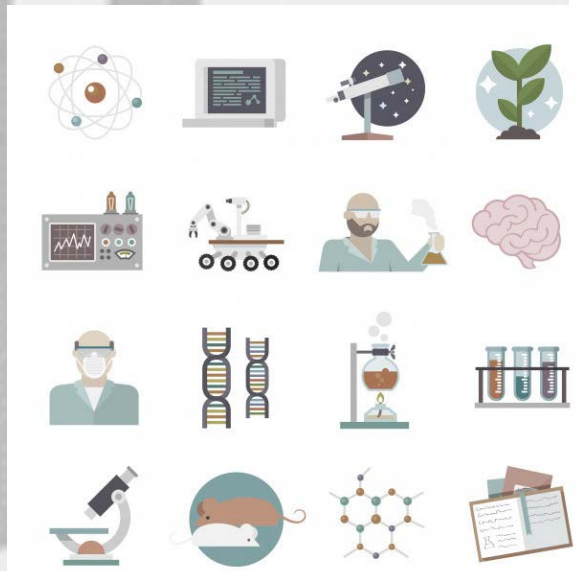
[…]

3. Involving people with dementia
4. Informed consent in dementia research
5. Protecting the wellbeing of people involved in dementia research
6. Risk, benefit, burden and paternalism

[…]

1) Informed consent
2) Proportionality of risk/burden and benefits
3) Fair research participant selection

[Focus on subject-subject relationships also in health research]



Historical background and contemporary regulations

Nuremberg doctors' trials

Sentencing of Nazi doctors involved in cruel human experiments with concentration camps detainees.

Development of the
Code of Nuremberg (1948):
Protection of human rights of research participants.

Historical background and contemporary regulations

The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential.

   This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.

   The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

Historical background and contemporary regulations

WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

Print PDF Send Follow Vind ik leuk 1.955 personen vinden dit leuk. Registreren om te zien wat je vrienden leuk vinden Adjust font size...

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964

and amended by the:

29th WMA General Assembly, Tokyo, Japan, October 1975

35th WMA General Assembly, Venice, Italy, October 1983

41st WMA General Assembly, Hong Kong, September 1989

48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

52nd WMA General Assembly, Edinburgh, Scotland, October 2000

53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)

55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)

59th WMA General Assembly, Seoul, Republic of Korea, October 2008

64th WMA General Assembly, Fortaleza, Brazil, October 2013

1964 **Favorable risk-benefit ratio**

1975 **Independent review**, intent to publish research results

Historical background and contemporary regulations

De wegwijzer naar informatie en diensten van alle overheden

Overheid.nl

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Wet- en regelgeving

› Zoeken › Regeling

‹ Naar zoeken

Wet medisch-wetenschappelijk onderzoek met mensen

Geldend van 01-03-2017 t/m heden

Wet van 26 februari 1998, houdende regelen inzake medisch-wetenschappelijk onderzoek met mensen (Wet medisch-wetenschappelijk onderzoek met mensen)

Alles openklappen

Alles dichtklappen

Opschrift

Aanhef

Paragraaf 1 Algemene bepalingen (Artikelen 1-2a)

Paragraaf 2 Regels voor wetenschappelijk onderzoek met proefpersonen (Artikelen 3-6)

Paragraaf 3 Aansprakelijkheid en verzekering (Artikel 7)

Paragraaf 4 Verplichtingen van diegenen die het wetenschappelijk onderzoek verrichten of uitvoeren (Artikelen 8-9)

Paragraaf 5 (Artikelen 10-13)

Wij Beatrix, bij de gratie Gods, Koningin der Nederlanden, Prinses van Oranje-Nassau, enz. enz. enz.

Allen, die deze zullen zien of horen lezen, saluut! doen te weten:

Alzo Wij in overweging genomen hebben, dat het, mede in verband met de artikelen 10 en 11 van de Grondwet, wenselijk is regelen te stellen met betrekking tot medisch-wetenschappelijk onderzoek met mensen;

Zo is het, dat Wij, de Raad van State gehoord, en met gemeen overleg der Staten-Generaal, hebben goedgevonden en verstaan, gelijk Wij goedvinden en verstaan bij deze:

Paragraaf 1. Algemene bepalingen

Artikel 1

1 In deze wet en de daarop berustende bepalingen wordt verstaan onder:

a. Onze Minister: Onze Minister van Volksgezondheid, Welzijn en Sport;

b. wetenschappelijk onderzoek: medisch-wetenschappelijk onderzoek waarvan deel uitmaakt het onderwerpen van personen aan handelingen of het opleggen aan personen van een bepaalde gedragswijze;

Alzheimer Europe Report

The ethics of dementia research

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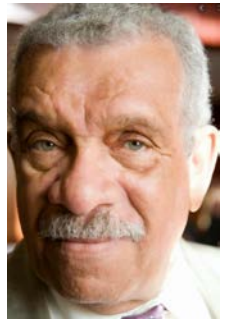
https://www.alzheimer-europe.org/Ethics/Ethical-issues-in-practice/2011-Ethics-of-dementia-research

Doing dementia research ethically: challenges posed by (possibly) demented participants

Peter

Respect his autonomy and provide genetic status?
Protect from unnecessary harm and withhold information meaningless on an individual basis?



Gordon

Respect of his autonomy to not be diagnosed or safeguard his well-being by providing care? Does he still have decision-making capacity?
Does his wife understand the goal of research (or therapeutic misconception)?

Carola

Safeguard her well-being and provide the best possible care?
Engage in research study with the possible benefit of a drug treatment and the –certain- risk of loosing daily care?

Research integrity

Bart Penders

https://mediasite.maastrichtuniversity.nl/Mediasite/Play/7b8f96070b7646dfad044a7c4a6ebaba1d

Questions?

Thank you - acknowledgements

Maastricht University
the institute of mental health Nottingham Research Excellence for Innovation
distINCT dementia: intersectorial strategy for training and innovation network for current technology
alzheimer nederland
ALZHEIMER CENTRUM LIMBURG
Alzheimer Europe
Alzheimer's Society United Against Dementia
INIERDEM Early detection and timely INTERvention in DEMentia
Pride Promoting independence in dementia
Improving Dementia Care ESRC·NIHR

INDUCT