

Ethics, Disease, and the Future of Health

Scale matters in cognitive bio-enhancement programs

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- **Why scale matters in the study of the feasibility of cognitive bio-enhancement programs**
 - If resources are enough to achieve the goals
 - Technologies involved have passed a rigorous evaluation
 - Resources are well dimensioned, specific, cost-efficient and validated
- **Moral implications**
 - Social cooperation and resources distribution
 - Underestimate technological developments (IT infraestruct., IA...)

Overview

- Viability of cognitive bio-enhancements programs
- Scenarios (primary, high school, university)
- Careful assessment of bio-enhancement technologies
- Inequalities in access to educational resources
- Scales of interventions
- Social context, institutional and cultural environment
- Socio-technical prospective
- Dystopian objections

Aim and objectives

- **Study the viability of cognitive bio-enhancements programs**
 - in verisimilar scenarios (primary, high school, university)
 - with reliable devices and substances (for medical uses)
 - considering the differences in initial conditions
 - educational resources and cultural environment
 - extracurricular learning support and inequalities in access to IT
 - considering scales of interventions
 - socio-technical prospective and dystopian objections

Background

- **Cognitive bio-enhancement as a challenge for moral deliberation in the present**
 - Short repertoire of technological options for humans
 - Not affordable for generalized use, except in clinical context
 - Most part remain as experimental, before the "proof of concept" phase
 - A few of them (neuromodulators) will be safe, specific and validated for medical uses
 - **Who could be eligible for its benefits?**
 - Childs, teenagers, students in universities, athletes...
 - Most likely, only very specific individuals/cases
 - Physiological approaches focused on pharmaceutical research

Background

Four main types of physiological interventions:

Genetic, pharmacologic, electro-magnetic, and surgical

– **Surgical** (primary physiological target is CNS):

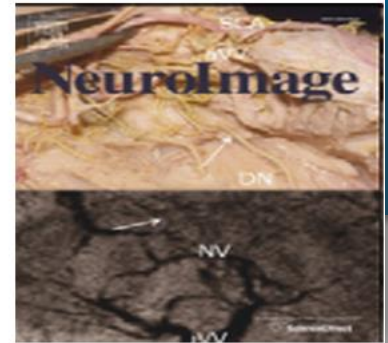
- (i) implantation of **neuroprostheses**, including brain-computer interfaces (“bionics”)
- (ii) intracranial grafting or **implantation of cells** (neural, non-neural, or embryonic stem cells) for **tissue repair** or cell-containing devices for the local delivery of bioactive compounds
- (iii) intracranial **gene transfer** techniques to enhance or dampen protein expression for cure
- (iv) techniques of **direct surgical, or electrical, stimulation of defined brain areas** for the functional treatment of nervous disorders such as epilepsy.

Enhancement of human cognitive performance using transcranial magnetic stimulation (TMS)

Bruce Luber*, Sarah H. Lisanby

Department of Psychiatry and Behavioral Sciences, Duke University, Durham, USA

Department of Psychology and Neuroscience, Duke University, Durham, USA



- Over sixty studies have reported significant improvements in speed and accuracy in a variety of tasks involving perceptual, motor, and executive processing.
- **Two basic categories** of enhancement mechanisms:
 - direct modulation of a cortical region or network that leads to more efficient processing,
 - and addition-by-subtraction (disruption of processing which competes or distracts from task performance).
- Potential applications of TMS cognitive enhancement for accelerated skill acquisition in healthy individuals
 - further refinements in the application of TMS to cognitive enhancement can still be made | questions remain regarding the mechanisms underlying the observed effects.

Direct-to-consumer TMS devices

- **Only 1 deep transcranial magnetic stimulation machine in Spain in Oct. 2015:** ([1](#), [2](#), [3](#))
 - Israeli company (**Brainsway LTD**) has the patent and markets it under "draconian" conditions:
 - **Brainsway does not sell the equipment: it rents for 3 years**
 - 60.000 - 110.000 EUR/year
 - Extra amount if >40 patients
 - 150 – 300 EUR/ session
 - 20 sessions in 4 – 12 weeks (usual treatment) = **3.900 EUR**
 - Extended fraudulent offer on the Internet in 2016-2017
 - **Risks of *direct to consumer* TMS devices** ([ej.1](#), vs [ej.2](#))
 - Maslen, H., Douglas, T., Cohen Kadosh, R., Levy, N., & Savulescu, J. (2014). **The regulation of cognitive enhancement devices: extending the medical model.** *Journal of Law and the Biosciences*, 1(1), 68–93. <http://doi.org/10.1093/jlb/lst003>
 - **Thync Vibes** (\$299)

Advertising based on testimonies (and some [refs.](#))

<http://www.brainsway.com/researchers-portal>

Depression patie

Researchers Portal

Home › Researchers Portal

Deep TMS Indications

OCD

Posttraumatic stress disorder

Smoking cessation

Bipolar disorder

Stroke

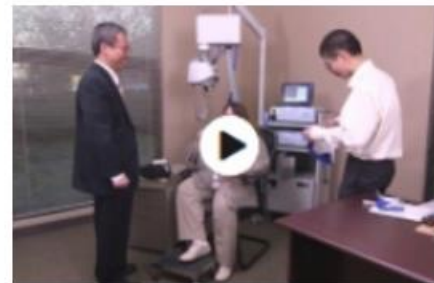
Chronic pain

Alzheimer's disease

Autism

Reinventing Brain Research

Brainsway* launches a new era in brain research, with Deep Transcranial Magnetic Stimulation, which effectively activates brain structures using directed electromagnetic fields.



Testimonial by Patient Treated with Brainsway TMS Therapy for Depression -

Lack of regulation for non-clinical use of TMS

http://www.oxfordmartin.ox.ac.uk/downloads/briefings/Mind_Machines.pdf

It is a confused situation given that the same kinds of devices are being trialled by scientists in clinical settings to potentially alleviate the symptoms of conditions such as depression or Parkinson's disease. Others are being developed to improve the concentration of people suffering with attention deficit hyperactivity disorder, or as a cure for insomnia. However, when no claim to therapeutic effect – either treatment or diagnosis – is made by the manufacturer, these devices can be considered to be cognitive enhancement devices (CEDs).

Proposal: Cognitive enhancement devices (CEDs)—such as transcranial direct current stimulators (tDCS) and transcranial magnetic stimulators (TMS)—should be regulated under medical devices legislation (for instance, the Medical Devices Directive (MDD) within the European Union).

Maslen, H., Douglas, T., Cohen Kadosh, R., Levy, N., & Savulescu, J. (2014). **The regulation of cognitive enhancement devices: extending the medical model.** *Journal of Law and the Biosciences*, 1(1), 68–93. <http://doi.org/10.1093/jlb/lst003>

Lack of regulation for non-clinical use

→ Definition of a CED / distinction treatment - enhancement

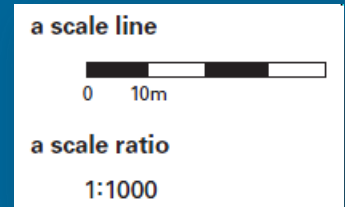
- **Maslen et al. (1) minimize the importance given to the treatment-enhancement distinction:**
 - If some devices are misclassified as therapeutic devices, this will not have major implications for their regulation: **What matters are risks and benefits.**
- The European Commission's proposed creation of **Annex XV for implantable and other invasive devices** for which the manufacturer claims only a non-medical purpose (2): **should include non-invasive neuromodulation for non-medical purposes**
- Maslen, Savulescu et al.: **There is a wealth of scientific research that provides proof of concept for the cognitive enhancing effects of tDCS and TMS techniques.**
- De Ridder, Vanneste, and Focquaert (3): there is currently 'no substantive evidence that CEDs produce lasting effects outside of research and clinical settings'.

(1) Maslen, H., Douglas, T., Cohen Kadosh, R., Levy, N., & Savulescu, J. (2015). **The regulation of cognitive enhancement devices: refining Maslen et al.'s model.** *Journal of Law and the Biosciences*, lsv029. <http://doi.org/10.1093/jlb/lsv029>

(2) http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf

(3) Dirk De Ridder, Sven Vanneste & Farah Focquaert, **Outstanding Questions Concerning The Regulation Of Cognitive Enhancement Devices**, 1 J. L. & Biosci. 316–21 (2014)

Example #1



- **Only 1 student undergoes medical treatment for cognitive enhancement in a secondary school center (20 groups and 600 students)**
 - Scale ratio: 1:600
 - Proportion: 0.17%
- Projection (Spain, 2014-2015):
 - 13.483 stud. in the country (Total: 8.090.017 non univ. students)
 - If cost/tto. = 5.000 EUR, total cost= 67.415.000 EUR
 - It means 2.697 profs. less (av. salary: 25.000 EUR/year).

Example #1

Justification

- The last alternative to compensate biological, genetic or neurophysiological impairments
- Reasonable expectations about restoring average cognitive functions, rather than improving or enhancing
- When the technologies involved are still experimental
 - Risk evaluation
 - Cost-efficiency
 - Priorities compatible with general interest
 - Informed consent

INICIO DEL CURSO ESCOLAR >

Un millón de alumnos más, 30.000 profesores menos

El número de alumnos por aula no podrá bajar este curso como anunció Educación, según CC OO. UGT pide menos horas de clase para los docentes



PILAR ÁLVAREZ 

Madrid - 15 SEP 2015 - 16:03 CEST



Impact of the Great Recession on spanish educational system

- 30.000 profs. less than in 2013
- 1.036.000 stud. more in the period of compulsory schooling

Changes in the ratio

- ✓ From 25 to 30 stud./class in Primary school
- ✓ 30 → 36 stud./class Secondary school
- ✓ 37 → 42 stud/ class in pre-universitary

Consequences

- Deterioration in key indicators (success ratio, dropout rate, average level in higher education...)
- Increased risk of social conflict, work stress and discomfort among professionals
- Lower perception of quality
- Reduction of opportunities for the next generations

Students under special support programs

Porcentaje de alumnado con necesidades educativas especiales. Curso 2014-2015

	Total ⁽¹⁾	E. Infantil	E. Primaria	ESO	Bachillerato	FP	PCPI y Otros prog. format.
TOTAL	2,2	0,9	2,3	2,4	0,4	0,9	9,7
Centros Públicos	2,3	1,1	2,7	2,6	0,4	0,8	8,3
Enseñanza concertada	2,2	0,6	1,6	2,3	0,6	1,2	20,7
Enseñanza privada no concertada	0,3	0,2	0,4	0,5	0,4	0,3	1,5
Hombres	2,8	1,2	3,0	3,2	0,6	1,0	9,0
Mujeres	1,5	0,6	1,5	1,7	0,3	0,6	11,1

(1) En el cálculo del Total se incluye el alumnado de Educación Especial específica.

Datos y cifras Ministerio de Educación, Cultura y Deporte. Curso escolar 2015/2016.

<http://www.mecd.gob.es/servicios-al-ciudadano-mecd/dms/mecd/servicios-al-ciudadano-mecd/estadisticas/educacion/indicadores-publicaciones-sintesis/datos-cifras/Datosycifras1617esp.pdf>

Teachers in the Andalusian educational system

Profesorado

	Público	Concertado	Privado	TOTAL
Maestros	49.990	10.188	1.462	61.640
Profesorado de Secundaria	39.066	8.456	2.952	50.474
Maestros de Ed. Permanente	2.171			2.171
Profesorado de Ens. Rég. Especial	3.903		405	4.308
TOTAL	95.130	18.644	4.819	118.593

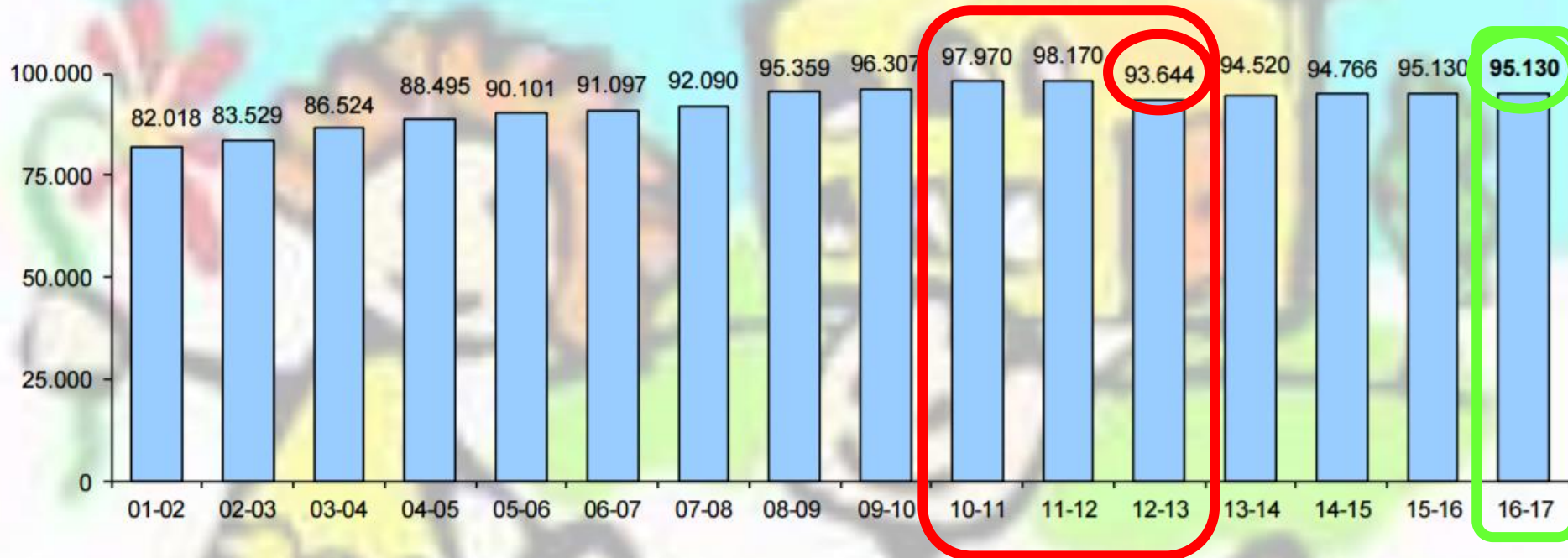
(*) No incluye el 1º ciclo de Educación Infantil

No se incluye el personal que realiza funciones de Inspección Educativa (285).

Estadísticas de la Consejería de educación, Junta de Andalucía. Datos estimativos 2016-2017.
<http://www.juntadeandalucia.es/educacion/webportal/ishare-servlet/content/b2ad15b9-959a-4ad3-96f6-ff1c560dae64>

Reduction of teachers in Andalusia (2011-2016)

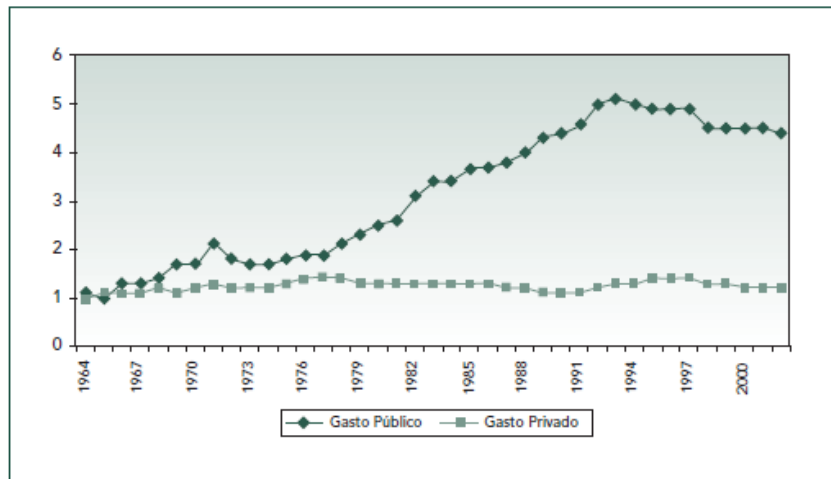
Evolución del profesorado en la Enseñanza Pública



No incluye el 1º ciclo de Educación Infantil.
No se incluye el personal que realiza funciones de Inspección Educativa (285).

Estadísticas de la Consejería de educación, Junta de Andalucía. Datos estimativos 2016-2017.
<http://www.juntadeandalucia.es/educacion/webportal/ishare-servlet/content/b2ad15b9-959a-4ad3-96f6-ff1c560dae64>

D.1. GASTO EN EDUCACIÓN SOBRE EL PIB



Fuente: Ministerio de Educación y Ciencia

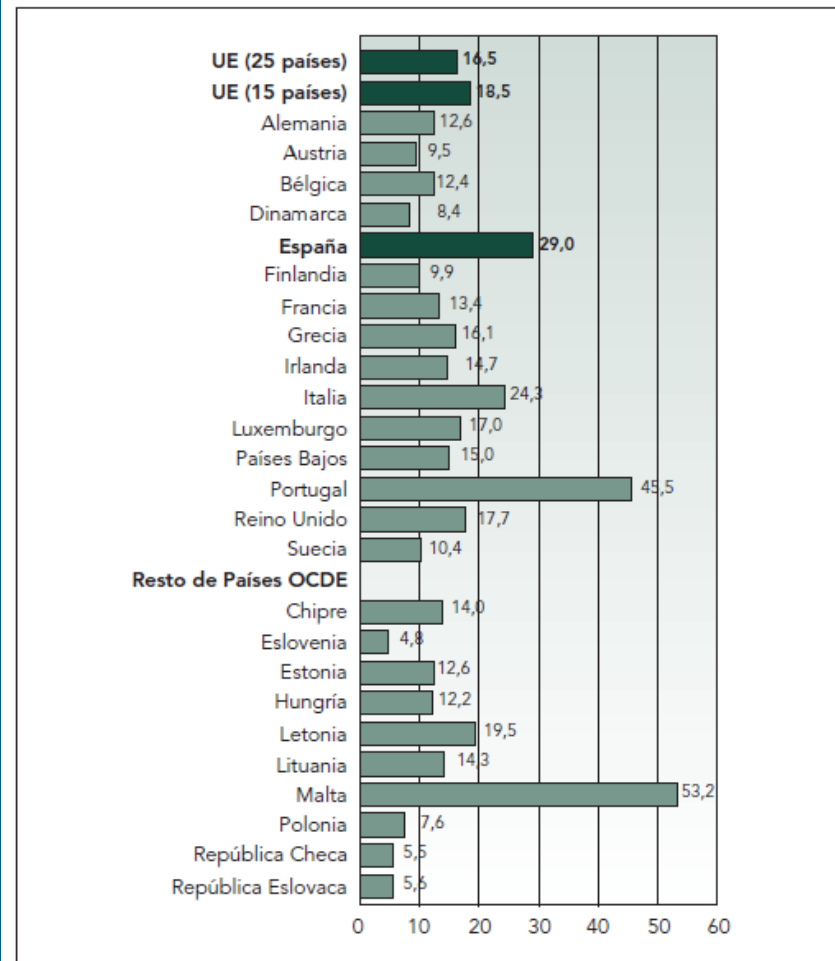
D.2. GASTO PÚBLICO EN EDUCACIÓN SOBRE EL PIB

	1970	1975	1980	1985	1995	1999	2000
ESPAÑA	1.7	1.8	2.5	3.7	4.7	4.5	4.3
Media UE	5.1	5.4	5.4	5.3	5.6	5.5	5.0
Media OCDE*	5.2	5.6	5.5	5.3	5.4	5.2	4.8

Fuente: OCDE (varios años).

Nota: * Las medias de la OCDE corresponden a un número variable de países, según los años.

A.9. ABANDONO EDUCATIVO TEMPRANO: PORCENTAJE DE POBLACIÓN ENTRE 18 Y 24 AÑOS QUE NO HA COMPLETADO LA E. SECUNDARIA 2ª ETAPA Y NO SIGUE NINGÚN TIPO DE ESTUDIO-FORMACIÓN. AÑO 2002



Ministerio de Educación y Ciencia. *Las cifras de la educación en España. Estadística e indicadores. 2004.* <http://debateeducativo.mec.es/pdf/anexo.pdf>

Socio-technical prospective and dystopian objections

Williams, S. J., Coveney, C. M., & Gabe, J. (2013). Medicalisation or customisation? Sleep, enterprise and enhancement in the 24/7 society. *Social Science & Medicine*, 79(0), 40–47. <http://doi.org/10.1016/j.socscimed.2012.07.017>

- **Sociological research on the medicalisation of sleep**
 - Prospective ‘customisation’ of sleep in the 24/7 society
 - How does it relate to the medicalisation of sleep
- **Extended use of drugs and technologies design to customize our sleep patterns** and practices to fit around the escalating temporal demands of daily life,
 - As helping remedy to compensate the increasing misalignment between biological and social time.
 - **Improving/optimize safety, productivity and performance in late modern society**, where alertness is prized, sleepiness is problematized and vigilance is valorised.
 - Relations between the biomedicalisation/customisation of sleep and a research agenda on the biopolitics of sleep and wakefulness.

Elements of *dystopian objection* in N. Agar

A Precautionary Approach to Radical Enhancement

This book presents a variety of possible futures that are somewhat darker than those favored by the advocates of radical enhancement. I conjecture that the most dramatic means of enhancing our cognitive powers could in fact kill us; that the radical extension of our life spans could eliminate experiences of great value from our lives; and that a situation in which some humans are radically enhanced while others are not could lead to a tyranny of posthumans over humans.

N. Agar, *Humanity's end: why we should reject radical enhancement*. Cambridge, MA: MIT Press, 2010: 11.

References

- Cabrera, L., & Weckert, J. (2013). Human Enhancement and Communication: On Meaning and Shared Understanding. *Science and Engineering Ethics*, 19(3), 1039–1056.
<http://doi.org/http://dx.doi.org/10.1007/s11948-012-9395-2>
- Dresler, M., Sandberg, A., Ohla, K., Bublitz, C., Trenado, C., Mroczko-Wąsowicz, A., ... Repantis, D. (2013). Non-pharmacological cognitive enhancement. *Neuropharmacology*, 64(0), 529–543.
Retrieved from <http://www.sciencedirect.com/science/article/pii/S0028390812003310>
- Maslen, H., Douglas, T., Cohen Kadosh, R., Levy, N., & Savulescu, J. (2014). The regulation of cognitive enhancement devices: extending the medical model. *Journal of Law and the Biosciences*, 1(1), 68–93. <http://doi.org/10.1093/jlb/lst003>
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- Hildt, E., & Franke, A. G. (2013). *Cognitive Enhancement. An Interdisciplinary Perspective*. (E. Hildt & A. G. Franke, Eds.) (Vol. 1). Dordrecht: Springer Netherlands. <http://doi.org/10.1007/978-94-007-6253-4>
- Williams, S. J., Coveney, C. M., & Gabe, J. (2013). Medicalisation or customisation? Sleep, enterprise and enhancement in the 24/7 society. *Social Science & Medicine*, 79(0), 40–47.
<http://doi.org/10.1016/j.socscimed.2012.07.017>