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### The ethics and legality of studying games with depressed participants

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## Η ηθική και η νομιμότητα της μελέτης των παιχνιδιών με καταθλιπτικούς συμμετέχοντες

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### Περίληψη

Αυτό το άρθρο εξετάζει το παιχνίδι ως θεραπεία για την κατάθλιψη, επικεντρώνοντας στο φινλανδικό παιχνίδι Meliora και την έρευνά του. Αναπτυγμένο από το Πανεπιστήμιο Aalto, το Meliora στοχεύει στην θεραπεία των καταθλιπτικών ατόμων μαζί με φάρμακα και θεραπεία. Η θεραπεία με το παιχνίδι είναι μια νέα καινοτομία και είναι επομένως απαραίτητο να διερευνηθούν οι νομικές και ηθικές διαστάσεις που προκύπτουν σε αυτές τις μελέτες.

Ο στόχος του άρθρου είναι να υποδείξει συγκεκριμένα ζητήματα που προκύπτουν κατά τη διενέργεια έρευνας με καταθλιπτικά άτομα. Ξεκινάει παρουσιάζοντας τη σχέση μεταξύ παιχνιδιού και ψυχικής υγείας, συζητώντας τα αρνητικά και θετικά αποτελέσματα του παιχνιδιού στο Κεφάλαιο 2. Στο Κεφάλαιο 3 παρουσιάζονται το Meliora και άλλες καινοτομίες στον ίδιο κλάδο μαζί με μια περιγραφή του ερευνητικού έργου. Στο Κεφάλαιο 4, επικεντρώνεται στα βιοηθικά και νομικά ζητήματα που σχετίζονται με την έρευνα με συμμετέχοντες που πάσχουν από κατάθλιψη. Τα ζητήματα συζητούνται στο πλαίσιο των τεσσάρων βιοιατρικών αρχών: σεβασμός της αυτονομίας, μη βλάβη, ευεργεσία και δικαιοσύνη. Το κεφάλαιο αναδεικνύει ανησυχίες που σχετίζονται με τη βλάβη και τους κινδύνους, την ενημέρωση για το συναίσθημα συναίνεσης ως καταθλιπτικό ή εθισμένο άτομο και τη δικαιολογία του αποκλεισμού συγκεκριμένων ομάδων από την έρευνα. Τέλος, το Κεφάλαιο 5 παρουσιάζει συνοπτικά τα πορίσματα.

**Λέξεις κλειδιά:** βιντεοπαιχνίδι, κατάθλιψη, ψηφιακός θεραπευτικά, παίγνια, ηθική και δεοντολογία, νόμος.

## The ethics and legality of studying games with depressed participants

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### Abstract

This article examines gaming as a treatment for depression, focusing on the Finnish game Meliora and its research. Developed by Aalto University, Meliora aims to improve mental health of de-pressed individuals in conjunction with drugs for depression and therapy. Gaming as treatment is an innovation, and therefore, it is essential to research the legal and ethical dimensions that arise in these studies.

The aim of the article is to indicate some specific issues that arise when conducting research on depressed people. It begins by presenting the relationship between gaming and mental health, discussing both the negative and positive effects of gaming in Chapter 2. Chapter 3 introduces Meliora and other innovations in the same industry along with a description of the research project. In Chapter 4, the focus is on bioethical and legal issues relating to research on depressed participants. The issues are discussed in light of the four biomedical principles: respect for autonomy, nonmaleficence, beneficence and justice. The chapter highlights concerns related to harm and risks, giving informed consent as a depressed or addicted individual, and the justification of excluding certain groups from the research. Finally, Chapter 5 provides a summary of the findings.

**Keywords:** video games, depression, digital therapeutics, gaming, ethic, law.

## 1. Introduction

The role of the video game industry has grown enormously over recent decades,<sup>1</sup> and it is increasingly important to understand its development and impacts. In various branches of science, researchers have studied the relationship between gaming and mental health.<sup>2</sup> While some have concluded that gaming has negative effects on mental health,<sup>3</sup> others have found that moderate gaming can improve a player's mental health.<sup>4</sup>

Currently, a brain researcher named Matias Palva from Aalto University in Finland is leading a research group that is developing a therapeutic video game called Meliora for depressed individuals. Meliora, a three-dimensional strategy game with a mission to save the world, could be used as a treatment for depression in combination with therapy and medication. The game's therapeutic potential lies in its ability to challenge players' thinking and create accomplished feelings for them as well as create a sense of connection with others. By restoring cognitive functions, the game aims to improve the overall mental health of players.<sup>5</sup> The project is now ongoing and Meliora is being tested with individuals who suffer from depression.

This article examines the potential of gaming as a treatment for depression, with a specific focus on the game Meliora and its effects on a player's health. The article also briefly mentions other innovative games developed both in Finland and in other countries. The aim of this article is to outline the research on Meliora, and the ethical considerations involved in testing games for depressed individuals. The article examines the risks and benefits of gaming in light of the four principles of biomedical ethics: respect for autonomy, nonmaleficence, beneficence, and justice, as well as in light of the relevant legislation, with a focus on the Oviedo Convention.

The purpose of this article is not to conclude whether testing and gaming Meliora or other games is acceptable in light of the principles and

<sup>1</sup> Video Game Market Size, Share & Trends Analysis Report 2030. Available at: <https://www.grandviewresearch.com/industry-analysis/video-game-market>. Accessed 6 February 2023; Boyle, EA, Connolly TM, Hainey T, Stansfield M. The role of psychology in understanding the impact of computer games. *Entertainment Computing* 2011, 272: 521-530, p. 69.

<sup>2</sup> See e.g., Li J, Theng YL, Foo S. Game-based digital interventions for depression therapy: a systematic review and meta-analysis. *Cyberpsychology, behavior and social networking* 2014, 17: 519-527. Available at: <https://doi.org/10.1089/cyber.2013.0481>.

<sup>3</sup> See e.g., Möller I, Krahé B. Exposure to violent videogames and aggression in German adolescents: a longitudinal analysis. *Aggressive Behavior* 2009, 35: 75-89. See also EA. Boyle, *op.cit.* and Wei HT, Chen MH, Huang PC, Bai Y-M. The association between online gaming, social phobia, and depression: an internet survey. *BMC Psychiatry* 2012, 12: 1-7. Available at: <https://doi.org/10.1186/1471-244X-12-92>.

<sup>4</sup> See e.g., Russionello C, O'Brien K, Parks JM. The effectiveness of casual video games in improving mood and decreasing stress. *Journal of Cyber Therapy and Rehabilitation* 2009, 2: 53-66; Jones CM, Scholes L, Johnson D, Katsikitis M, Carras MC. Gaming well: links between videogames and flourishing mental health. *Frontiers in Psychology*, 2014, 260: 1-8; Kowal M, Conroy E, Ramsbottom N, Smithies T, Toth A, Campbell M. Gaming Your Mental Health: A Narrative Review on Mitigating Symptoms of Depression and Anxiety Using Commercial Video Games. *JMIR Serious Games* 2021, 9: 1-13. Available at: <https://games.jmir.org/2021/2/e26575>.

<sup>5</sup> Aalto University. Researchers develop a digital therapy to alleviate the symptoms of depression 21 October 2022. Available at: <https://www.aalto.fi/en/news/researchers-develop-a-digital-therapy-to-alleviate-the-symptoms-of-depression>. Accessed 20 February 2023. The article was written at the beginning of 2023.

legislation. Rather, the article aims to highlight the relevant issues that researchers should emphasize when conducting game research with depressed individuals. By doing so, this article aims to facilitate further research in the area of gaming as a potential treatment for mental health issues.

## 2. The Relationship Between Gaming and Health

Researchers have found various negative consequences of online gaming, particularly related to excessive gaming. Physical effects such as reduced physical activity, increased use of alcohol and tobacco,<sup>6</sup> lack of sleep,<sup>7</sup> and muscle soreness<sup>8</sup> are common consequences. Excessive gaming can also lead to problems with socializing, working, and education but it can also boost aggression, hostility, and inattention.<sup>9</sup> Negative mental health effects such as depression, social anxiety, isolation, generalized anxiety disorder, and attention deficit have also been linked to excessive gaming.<sup>10</sup>

While these effects are often associated with game addiction, they are not always directly related to it. For example, muscle soreness may

occur due to extended periods of sitting and gaming, regardless of addictive behavior. However, World Health Organization (WHO) recognizes gaming as a disorder that has a place in the 11th Revision of the International Classification of Diseases (ICD-11).<sup>11</sup> The disorder includes consequences related to the pattern of gaming, such as significant impairment in personal, social, and educational areas of functioning.<sup>12</sup> While gaming can have negative effects, it is primarily problematic for players who are classified as addicted or engaged

<sup>6</sup> Kim Y, Park JY, Kim SB, Jung I-K, Lim YS, Kim J-H. The effects of Internet addiction on the lifestyle and dietary behavior of Korean adolescents. *Nutrition Research and Practice* 2010, 4: 51-57.

<sup>7</sup> Kuss DJ, Griffiths MD, Binder JF. Internet addiction in students: Prevalence and risk factors. *Computers in Human Behavior* 2013, 29: 959-966. Available at: <https://doi.org/10.1016/j.chb.2012.12.024>, p. 127.

<sup>8</sup> HT. Wei et. al., *op.cit.*, p. 5.

<sup>9</sup> DJ. Kuss, MD. Griffiths & JF. Binder, *op.cit.*, p. 127.

<sup>10</sup> See e.g., Bernardi S, Pallanti S. Internet addiction: a descriptive clinical study focusing on comorbidities and dissociative symptoms. *Comprehensive Psychiatry* 2009, 50: 510-516. Available at: <https://doi.org/10.1016/j.comppsy.2008.11.011>.

<sup>11</sup> World Health Organization (WHO), Gaming Disorder. Available at: <https://www.who.int/standards/classifications/frequently-asked-questions/gaming-disorder>. Accessed 4 February 2023.

<sup>12</sup> ICD-11 for Mortality and Morbidity Statistics. 6C51 Gaming disorder, January 2023. Available at: <https://icd.who.int/browse11/l-m/en#/http://id.who.int/icd/entity/1448597234> Accessed 5 February 2023. To read more about a need to standardize gaming disorder, see Darvesh N, Radhakrishnan A, Lachance CC, Nincic V, Sharpe JP, Ghassemi M, Straus SE, Tricco AC. Exploring the prevalence of gaming disorder and Internet gaming disorder: a rapid scoping review. *Systematic Reviews* 2020, 68. Available at: <https://doi.org/10.1186/s13643-020-01329-2>. See more about the Internet Gaming Disorder; Bonnaire C, Baptista D. Internet gaming disorder in male and female young adults: The role of alexithymia, depression, anxiety and gaming type. *Psychiatry Research* 2019, 272: 521-530. Available at: <https://doi.org/10.1016/j.psychres.2018.12.158>; Liu L, Yao Y-W, Li C-SR, Zhang J-T, Xia C-C, Lan J, Ma S-S, Zhou N, Fang, X-Y. The Comorbidity Between Internet Gaming Disorder and Depression: Interrelationship and Neural Mechanisms. *Frontiers in Psychiatry* 2018, 154: 1-10; Schivinski B, Brzozowska-Woś M, Buchanan EM, Griffiths MD, Pontes HM. Psychometric Assessment of the Internet Gaming Disorder Diagnostic Criteria: An Item Response Theory Study. *Addictive Behaviors Reports* 2018, 30: 176-184.

in problematic playing.<sup>13</sup> According to WHO, gaming disorder is not a notably common phenomenon,<sup>14</sup> and only 3.05 % of gamers met the criteria for a gaming disorder in 2021.<sup>15</sup>

Studies have indicated that gaming can have positive effects on mental health by causing positive emotions, reducing stress,<sup>16</sup> and improving a player's self-esteem.<sup>17</sup> Additionally, gaming can improve various skills, such as communication skills.<sup>18</sup> Moderate gaming has been also associated with lower rates of substance use and risky behavior, as well as more balanced relationships and increased interest in school.<sup>19</sup>

Due to the length of this article, it is not possible to provide a comprehensive discussion of all the positive or negative effects of gaming. However, the findings indicate that the effects of gaming can vary depending on individual factors, such as the amount of time spent playing. For instance, the findings present that gaming can both increase and decrease the use of alcohol and tobacco, making it difficult to unambiguously identify the negative and positive effects of gaming. Additionally, certain risk factors, such as male gender, may increase the

likelihood of developing problems with gaming.<sup>20</sup>

Overall, especially excessive gaming can negatively affect psychosocial and physical well-being. However, it is important to note that gaming can also be a coping mechanism for those who suffer from mental health issues.<sup>21</sup> The effects are thus partially individual but there are both negative and positive effects related to gaming.

### 3. Games as a Treatment

#### 3.1. Finnish Innovations

##### 3.1.1. *Meliora*

*Meliora* is a first-person shooter game developed by the research group from Aalto University, and it also includes a strategic aspect. The game consists of a three-dimensional environment where a player has a mission to save the world by solving different challenges, including stopping creatures from plaguing the world. Unlike typical entertainment games, *Meliora* aims to provide experiences that can potentially help players with depression by utilizing its competitive nature and complex features.<sup>22</sup> The game's function of decreasing

<sup>13</sup> See e.g., Sublette VA, Mullan B. Consequences of Play: A Systematic Review of the Effects of Online Gaming. *International Journal of Mental Health and Addiction* 2012, 10: 3-23.

<sup>14</sup> WHO, *op.cit.*

<sup>15</sup> Stevens MWR, Dorstyn D, Delfabbro PH, King DL. Global prevalence of gaming disorder: A systematic review and meta-analysis. *Australian & New Zealand Journal of Psychiatry* 2021, 55: 553-568.

<sup>16</sup> CM. Jones et. al. *op.cit.*, p. 2-3.

<sup>17</sup> Durkin K, Barber B. Not so doomed: computer game play and positive adolescent development. *Journal of Applied Developmental Psychology* 2002, 23: 373-92.

<sup>18</sup> EA. Boyle, TM. Connolly, and M. Stansfield, *op.cit.*, p. 71.

<sup>19</sup> K. Durkin and B. Barber, *op.cit.*, p. 385-387.

<sup>20</sup> HT. Wei et. al., *op.cit.*, p. 5-6.

<sup>21</sup> Lemmens JS, Valkenburg PM, Peter J. Psychosocial causes and consequences of pathological gaming. *Computers in Human Behavior* 2011, 27: 144-152. Available at: <https://doi.org/10.1016/j.chb.2010.07.015>.

<sup>22</sup> Aalto University. Researchers developing computer game to treat depression 13 January 2021. Available at: <https://www.aalto.fi/en/news/researchers-developing-computer-game-to-treat-depression>. Accessed 6 February 2023; Aalto University, 21 October 2022, *op.cit.* You can see the video of *Meliora* at Kymäläinen S. Tältä näyttää kaksi miljoonaa euroa maksanut suomalainen toimintapeli, joka on tarkoitettu masennuksen hoitoon. *Yle Uutiset* 16



depression is based on the challenges it arranges for players and their ability to process information.<sup>23</sup> Meliora is an online game that falls under the category of Digital therapeutics (DTx) as it tries to offer a therapeutic intervention for depressed players.<sup>24</sup>

A therapeutic video game must be competitive enough to positively affect a player's brain because competitive games, where players must do their best to succeed, can have beneficial effects on mental health.<sup>25</sup> Therefore, it is expected that targeted video games, like Meliora, could alleviate the symptoms of brain diseases that were assumed to be permanent.<sup>26</sup> Games for depressed individuals have also other unique demands: for example, they cannot be too cheerful, as exaggerated happiness may annoy those who suffer from depression.<sup>27</sup>

The research group has recognized that gaming can cause negative consequences and a game for depressed individuals must have the characteristics that help with depression, not cause any other problems.<sup>28</sup> Meliora is not, at least for now, intended to be the sole treatment when treating depression and it should be used in combination with therapy and drugs.<sup>29</sup> However,

Meliora's value lies in its ability to focus on restoring cognitive functions that traditional treatments may not directly focus on. In addition, using a game as a treatment is cheaper than traditional drugs and therapies, its distribution is easier, and there are not the same side effects that relate to drugs.<sup>30</sup> Thus, when successful, gaming can be a credible alternative to other treatments.

### 3.1.1.1. Testing Meliora

Participating in testing Meliora involves playing Meliora and if a participant desires, participating in a brain study or a game-experience interview. Players must first play the game for 12 weeks and another 12 weeks of the study consists of observing the players. It is recommended that a player should play at least 24 hours per a gaming period. Playtime is, however, restricted, and each player can play 90 minutes per day at the most.<sup>31</sup> During the brain study, the research group will use MEG, MK, and TMS-EEG methods for testing.<sup>32</sup> Even though the intervention research of brain scan and brain stimulation is one of the biggest that has ever been done for depressed people,<sup>33</sup> the distinctive features of the interview and brain study of Meliora are not discussed in this article.

Clinical trials involve the study of new tests and treatments, evaluating their results and effects on human health outcomes. Medical interventions such as drugs, behavioral treatments, and preventive care can be studied

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November 2022. Available at: <https://yle.fi/a/74-20004624>. Accessed 13 April 2023.

<sup>23</sup> Aalto University, Tutkimuksen tiedote. <https://nttk-psx-19.biocenter.helsinki.fi/meliora/index.php/info>. Accessed 11 February 2023.

<sup>24</sup> See the definition: Digital Therapeutics Alliance, Digital Therapeutics Definition and Core Principles. [https://dtxalliance.org/wp-content/uploads/2021/01/DTA\\_DTx-Definition-and-Core-Principles.pdf](https://dtxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Definition-and-Core-Principles.pdf). Accessed 8 February 2023.

<sup>25</sup> S. Kymäläinen, *op.cit.*

<sup>26</sup> Aalto University, 13 January 2021, *op.cit.*

<sup>27</sup> S. Kymäläinen, *op.cit.*

<sup>28</sup> S. Kymäläinen, *op.cit.*; Aalto University, 21 October 2022, *op.cit.*

<sup>29</sup> Aalto University, 13 January 2021, *op.cit.*; Aalto University, 21 October 2022, *op.cit.*

<sup>30</sup> S. Kymäläinen, *op.cit.*

<sup>31</sup> Aalto University, University of Helsinki. Rekrytointi-ilmoitus. Videopelien vaikutus masennuksen oireisiin ja aivotoiminnan dynamiikkaan. <https://nttk-psx-19.biocenter.helsinki.fi/meliora/>. Accessed 30 January 2023.

<sup>32</sup> S. Kymäläinen, *op.cit.*

<sup>33</sup> *Ibidem.*

through clinical trials.<sup>34</sup> In the case of Meliora, testing concerns gaming, which can be considered a medical intervention. Therefore, testing Meliora is a form of clinical trial. As there is no promise of any clear medical benefits for a participant, the research is considered non-therapeutic research that benefits medicine and a larger group rather than a singular participant.<sup>35</sup> Additionally, the final aim of the research is to develop modern treatment methods for people who suffer from depression.<sup>36</sup>

Meliora has a previous version that was tested earlier for eight weeks.<sup>37</sup> After the research, the research group noticed that gaming both mitigated depression symptoms and restored cognitive abilities. The results, however, were not as significant as with traditional depression treatments.

### 3.1.2. Other Innovations

There are also other digital innovations related to cognitive function and mental health in Finland. For example, a virtual reality game named EPELI, developed by Aalto University, can track a player's eye movements, and use machine learning to find differences in people with ADHD. The researchers behind the game

also see a possibility to rehabilitate ADHD with gaming and are willing to develop gamification-based digital therapies for children with ADHD in the future.<sup>38</sup>

Innovations have been developed in other countries as well. One innovation is a video game called Thymia which is based on using a player's voice, movement, and behavioural data when identifying conditions and symptoms of mental illness.<sup>39</sup> Thymia has the potential to be a helpful tool in improving mental health.<sup>40</sup> Additionally, other games, such as The Guardians,<sup>41</sup> promise to improve a player's mental health.<sup>42</sup> Finally, we can mention the game named EndeavorRX which is designed for children with ADHD. It is the first game dealing with ADHD,<sup>43</sup> and thus it is based on the same aim as EPELI. Overall, many games have been developed to improve mental health.

<sup>34</sup> See e.g., World Health Organization (WHO), Clinical trials. [https://www.who.int/health-topics/clinical-trials#tab=tab\\_1](https://www.who.int/health-topics/clinical-trials#tab=tab_1). Accessed 16 February 2023.

<sup>35</sup> See about the distinction section 6 of the WMA Declaration of Helsinki. World Medical Association (WMA), Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>. See also Hallituksen esitys Eduskunnalle laeiksi lääketieteellisestä tutkimuksesta sekä potilaan asemasta ja oikeuksista annetun lain 6 ja 9 §:n muuttamisesta 229/1998 vp, p. 6.

<sup>36</sup> Aalto University, Tutkimuksen tiedote, *op.cit.*

<sup>37</sup> In a joint clinical study by HUS Psychiatry, University of Helsinki, and Mielenterveystalo.

<sup>38</sup> Aalto University, 20 December 2022, *op.cit.*

<sup>39</sup> thymia, Making mental health visible. Available at: <https://thymia.ai/>. Accessed 14 April 2023. Thymia is developed in the UK.

<sup>40</sup> Zeitchik, S. Can a video game tell if you're depressed? 28 April 2022. The Washington Post. Available at: <https://www.washingtonpost.com/technology/2022/04/28/video-game-depression-thymia/>.

<sup>41</sup> Developed in the US.

<sup>42</sup> Forneua D, Ferguson C. Project: The Guardians. Affective Computing. Available at: <https://www.media.mit.edu/projects/guardians/overview/>. Accessed 14 February 2023.

<sup>43</sup> Developed in the US. Future London Academy. 5 Games That Improve Mental Health 16 August 2022. Available at: <https://futurelondonacademy.co.uk/en/articles/ux-5-games-for-mental-health>. Accessed 14 February 2023.



#### 4. A Framework for Ethical and Legal Game Research

The development of ethical guidelines for research began with The Nuremberg principles.<sup>44</sup> Research activities are controlled by several national and international ethical guidelines and recommendations, principles, and legislation, which have been developed to prevent such human rights violations that have been committed in the past, for example, by Nazi Germany.<sup>45</sup> Important ethical guidelines for medical research include, for example, the Declaration of Helsinki and its complement, the Declaration of Taipei.<sup>46</sup> In addition to ethical guidelines, human rights agreements regulate research activities.<sup>47</sup> For instance, Article 1 of the Charter of Fundamental Rights of The European Union states that human dignity is inviolable and it must be respected and protected. In addition to these, there exist numerous other regulations that regulate research activities.

The Oviedo Convention is the first legally binding multilateral instrument in the biomedical field, and it institutionalized bioethical principles as a binding instrument.<sup>48</sup> Therefore, it is the leading instrument concerning the protection of human rights in the biomedical field.<sup>49</sup> The Oviedo Convention bans the cruelest violations of human rights and serves as a legal framework for the biomedical field.<sup>50</sup>

The aim of the Oviedo Convention and other regulations is to protect the dignity and identity of all human beings. They also aim to guarantee respect for everyone's integrity and other rights, as well as fundamental freedoms during research and medical interventions.<sup>51</sup> In research, the starting point is that the interests and welfare of the human being shall prevail over the sole interest of society or science.<sup>52</sup>

<sup>44</sup> United Nations, Principles of International Law Recognized in the Charter of the Nürnberg Tribunal and in the Judgment of the Tribunal. Available at: [https://legal.un.org/ilc/texts/instruments/english/draft\\_articles/7\\_1\\_1950.pdf](https://legal.un.org/ilc/texts/instruments/english/draft_articles/7_1_1950.pdf).

<sup>45</sup> See e.g., Lehtonen L, Himberg J-J, Bardy A. *Kliinisen lääketutkimuksen etiikka, normit, ohjeet ja valvonta*. In Huupponen R. et al. (Eds.) *Kliininen farmakologia ja lääkehoito*. Kandidaattikustannus Oy, 2002: 918-931. See also Beauchamp, TL, Childress JF. *Principles of Biomedical Ethics* (7th edition). Oxford University Press 2013, p. 120-121.

<sup>46</sup> World Medical Association (WMA), Declaration of Taipei. Research on Health Databases, Big Data and Biobanks. Available at: <https://www.wma.net/what-we-do/medical-ethics/declaration-of-taipei/>. See additionally e.g., Council for International Organizations of Medical Sciences and World Health Organization. *International Ethical Guidelines for Health-related Research Involving Humans*. Available at: [https://cioms.ch/wp-](https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf)

[content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf](https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf).

<sup>47</sup> See e.g., Article 7 of the International Covenant on Civil and Political Rights. United Nations, International Covenant on Civil and Political Rights. <https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-civil-and-political-rights>.

<sup>48</sup> Andorno R. The Oviedo Convention: A European Legal Framework at the Intersection of Human Rights and Health Law. *Journal of International Biotechnology Law* 2005, 2: 133-143. Available at: <https://doi.org/10.1515/jibl.2005.2.4.133>.

<sup>49</sup> Article 1 of the Oviedo Convention. Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164, Oviedo Convention). Available at: <https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treaty-num=164>. See also Lehtonen L. *Bio-oikeus lääketieteessä*. Edita Publishing Oy 2006, p. 240.

<sup>50</sup> R. Andorno, *op.cit.*

<sup>51</sup> Article 1 of the Oviedo Convention, and L. Lehtonen, *op.cit.*, p. 240.

<sup>52</sup> Article 2 of the Oviedo Convention.

As the Oviedo Convention does not regulate specific issues, the four bioethical principles remain relevant in research ethics.<sup>53</sup> The principles are respect for autonomy, nonmaleficence, beneficence, and justice.<sup>54</sup> Applying these principles in research ensures that human dignity and ethical aspects are respected, and research ethics is in a central position during the whole research.<sup>55</sup>

The principles and legislation may regulate the same issues. It can be understood that legislation defines the minimum level of ethics of research, while research ethics defines its maximum level.<sup>56</sup> The bioethical principles are thus independent of, e.g., politics, and they must be seen as guiding values when considering research, as regulations are the tools that give a binding nature to these principles. Finally, the principles are considered *prima facie* obligations, which means that they should be followed if there is not a stronger or equal obligation.<sup>57</sup> In summary, all legally allowed actions are not ethically allowed, and ethics and regulation may regulate the same issue. Additionally, the principles may sometimes conflict with each other, and there is no clear hierarchy between the principles.<sup>58</sup>

This article focuses on the Oviedo Convention and its rules that institutionalize bioethical principles, and legal and ethical dimensions are discussed together. Other regulation, for example, the Additional Protocol

to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (CETS No. 195) is not discussed in this article as it is not ratified in Finland and therefore not binding in the case of Meliora. Furthermore, since gaming cannot be defined as a drug, the Act on Clinical Trials on Medicinal Products and Regulation (EU No 536/2014) of The European Parliament and of The Council on clinical trials on medicinal products for human use is not applicable in the case of Meliora.

#### 4.1. Respect for Autonomy

The principle of respect for autonomy is based on a person's free decision-making and autonomous choices. According to Beauchamp and Childress, personal autonomy is at least "self-rule that is free from both controlling interference by others and from limitations". This means that individuals must have the right to make choices about their actions and participate in activities, such as research.<sup>59</sup> The starting point is that an individual has the right to hold views, make choices and take actions based on personal values and beliefs.<sup>60</sup>

According to Beauchamp and Childress, an autonomous actor acts *intentionally, with understanding and without controlling influences that determine their action*. It is still necessary to ensure that a research participant is aware of the terms of the study and can freely choose to participate or decline the terms.<sup>61</sup> Before giving informed consent to participate, a participant must also be fully informed about the potential benefits and risks of the research, as well as any other significant factors related to their

<sup>53</sup> R. Andorno, *op.cit.*

<sup>54</sup> TL. Beauchamp and JF. Childress, 2013, *op.cit.*, p. 13.

<sup>55</sup> Nurmi, S-M. Miten mahdollistuu eettisesti kestävä kliininen tutkimus? Sosiaalilääketieteellinen Aikakauslehti 2019, 56: 65-67. Available at: <https://doi.org/10.23990/sa.75848>.

<sup>56</sup> *Idem*, p. 66.

<sup>57</sup> Beauchamp TL, Childress JF. Principles of Biomedical Ethics (5th edition). Oxford University Press 2001, p. 15.

<sup>58</sup> TL. Beauchamp and JF. Childress, 2013, *op.cit.*, p. 101.

<sup>59</sup> TL. Beauchamp and JF. Childress, 2001, *op.cit.*, p. 101.

<sup>60</sup> *Idem*, p. 63.

<sup>61</sup> TL. Beauchamp and JF. Childress, 2013, *op.cit.*, p. 104-105.

involvement.<sup>62</sup> Informed consent and autonomy are related to each other, and informed consent cannot be given without autonomy.<sup>63</sup> Although Beauchamp and Childress list seven elements of informed consent, this article accepts the prevailing and more common opinion that there are five elements of informed consent: *competence, disclosure, understanding, voluntariness, and consent.*<sup>64</sup>

The Oviedo Convention regulates informed consent in Chapter 2. According to Article 5, an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time. Additionally, according to Article 16(v) of the Oviedo Convention, research on a person may only be undertaken if the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. In addition, such consent may be freely withdrawn at any time.

#### 4.1.1. Issues With Respect for Autonomy

In the case of Meliora, the starting point is that participants have acted autonomously, and *intentionally*, when they have had a possibility to fill out the consent form without any pressure, and they know they can suspend their participation at any stage of the study before its

end without any harm to them.<sup>65</sup> However, even in this case, there is an issue with the validity of consent when consent is given via the Internet and without any authentication. Therefore, consent should be given again before the research begins to ensure that it is intended to be given.

In cases of testing games with people with mental health issues, one of the biggest issues concerns the autonomy and informed consent of participants. Mental health issues might, for example, affect a person's ability to think clearly and make informed decisions.<sup>66</sup> It may thus be problematic to determine whether participants with mental health issues are acting freely and if they can give their informed consent to research. Therefore, the issue is acting *with understanding*, and it is important to consider whether all depressed participants can give valid consent during the research.

The same problem is with addicted video players.<sup>67</sup> Participation of addicted players has, however, tried to restrict, and the consent form of Meliora includes that a participant who participates in the research, cannot be addicted to digital games, have a psychotic disease, be incapacitated or have any neurological disease.<sup>68</sup>

<sup>62</sup> TL. Beauchamp and JF. Childress, 2001, *op.cit.*, p. 77.

<sup>63</sup> Sellinger CP. The right to consent: Is it absolute? BJMP 2009, 2: 50-54. Available at: <https://www.bjmp.org/content/right-consent-it-absolute>.

<sup>64</sup> See e.g., TL. Beauchamp and JF. Childress, 2013, *op.cit.*, p. 124 and Varkey B. Principles of Clinical Ethics and Their Application to Practice. Med Princ Pract 2021, 30: 17-28.

<sup>65</sup> Author's translation. See Aalto University, Tutkimuksen tiedote, *op.cit.*, and Aalto University, Suostumuslomake. <https://nttk-psx-19.biocenter.helsinki.fi/meliora/index.php/consent>. Accessed 11 February 2023.

<sup>66</sup> See about the problems e.g., MedicalNewsToday. How does depression affect the body? 9 July 2018. Available at: <https://www.medicalnewstoday.com/articles/322395>. Accessed 1 April 2023.

<sup>67</sup> See e.g., Leby N. Addiction, Autonomy, and Informed Consent: On and Off the Garden Path. The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine 2016, 41: 56-73. Available at: <https://doi.org/10.1093/jmp/jhv033>, which discusses about drug addiction and autonomy.

<sup>68</sup> See Aalto University, Suostumuslomake, *op.cit.*

While these restrictions can be seen as a protective measure of participants, they also help to ensure the understanding of participants. Addiction may, however, be hardly noticeable, and researchers must be even more careful in ensuring that participants understand the risks involved in the research. Further challenges arise in depressed or addicted participants' inability to recognize the symptoms of addiction or other risks associated with the research.

As Meliora and other similar innovations involve research on individuals with depression or addiction, it is important to exercise greater caution than in research with non-depressed individuals or in research unrelated to addictive behavior. In the case of Meliora, some groups, such as addicts, prisoners, and people with diminished autonomy,<sup>69</sup> are not able to participate at all.<sup>70</sup> Even though these restrictions have been placed, careful observation during the research process is necessary to ensure ethical and responsible practices.

The ability to give valid consent relates to other dimensions as well. In the research of Meliora, no direct health benefits are promised or even expected for participants.<sup>71</sup> The starting point is that, according to Article 17(ii) of the Oviedo Convention, research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if the results of the research must have the potential to produce real and direct benefit to his or her health. However, research may be permitted under Article 17.1 if it meets all other conditions and additionally aims to contribute, through significant improvement in the scientific understanding of the individual's condition,

disease, or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition and if the research entails only minimal risk and minimal burden for the individual concerned.<sup>72</sup>

Since the final aim of the research is to develop modern treatment methods for people who suffer from depression and not directly benefit participants, it may be ethically and legally questionable to research Meliora on participants without the capacity to consent, such as those with depression. However, if a participant with diminished autonomy is used as a research subject, the risks and burdens, as well as the significance of the research, must be carefully examined.

Finally, the specific issue of Meliora is its novelty and potential side effects of the research. The consent form mentions some side effects, such as migraines and headaches,<sup>73</sup> but as gaming as a treatment for depression is an innovation, all risks and harms are not clear before the research. Some possible negative effects of gaming, such as addiction and anxiety, were examined in Chapter 2. However, it was also examined that the effects are different. Therefore, effects might differ between, for example, healthy and unhealthy participants, making it challenging to determine if participants are sufficiently informed and can give valid consent, particularly when considering a new form of treatment and when every possible side effect cannot be recognized. It is also unclear whether the research group should be more knowledgeable about possible side effects or not, or whether they should be informed when

<sup>69</sup> TL. Beauchamp and JF. Childress, 2001, *op.cit.*, p. 58.

<sup>70</sup> See Aalto University, Suostumuslomake, *op.cit.*

<sup>71</sup> See Article 17.1(ii) of the Oviedo Convention and Aalto University, Tutkimuksen tiedote, *op.cit.*

<sup>72</sup> Article 17.2(i)-17.2(ii) of the Oviedo Convention.

<sup>73</sup> See Aalto University, Tutkimuksen tiedote, *op.cit.*

acknowledging that, for example, addiction is a rare consequence and game time is restricted during the research.

When considering acting without controlling influences, it is recognized that people's actions are not often, if ever, fully autonomous, and it is not even the purpose. Substantially autonomous decisions are enough.<sup>74</sup> In the research of Meliora, there are no specific concerns regarding controlling influences. For example, the compensation for the research is legally justifiable,<sup>75</sup> and other concerns are not evident.

Overall, there appears to be a strong emphasis on respecting autonomy in the case of Meliora, even though there are some challenges related to autonomy and obtaining valid consent. Most of the problems are not unique to Meliora, and therefore, it is not necessary to consider them further in this article. The main concern here is with depressed and addicted individuals who may not be capable of assessing their ability to participate in the research, especially when considering the potential benefits and risks for participants. In this article, it cannot be concluded whether respect for autonomy is fully fulfilled both ethically and legally, but we have explored some possible risks of the research of Meliora and other similar research in the future.

#### 4.2. Beneficence and Nonmaleficence

The principle of nonmaleficence demands that no harm is inflicted on others in research. Although the hierarchy of ethical principles is not always clear, nonmaleficence is often

considered the primary principle in healthcare. The principle of beneficence is closely related to nonmaleficence but goes further by requiring positive steps to be taken to help others.<sup>76</sup> Therefore, beneficence demands that research must benefit someone or some group, while nonmaleficence only demands avoiding harm. Additionally, researchers must choose activities that are in the best interest of the subject and avoid inappropriately burdensome methods.<sup>77</sup>

According to Beauchamp and Childress, harm is defined as a setback or defeat of someone's interests, but not all harmful actions are necessarily wrong or unjustified.<sup>78</sup> Risks or even harms are not always prohibited, and they can sometimes be justified by more important interests.<sup>79</sup> The rule of double effect (RDE) is a tool that can help determine whether caused harm is acceptable in the research.<sup>80</sup> However, as emphasized earlier, this article only highlights harms and does not estimate them more, for example with the help of RDE.

Both principles are regulated in the Oviedo Convention. According to Article 16(ii) of the Oviedo Convention, the risks which may be incurred by that person cannot be disproportionate to the potential benefits of the research.<sup>81</sup> Article 2 of the Oviedo Convention also regulates that the interests and welfare of the

<sup>74</sup> TL. Beauchamp and JF. Childress, 2001, *op.cit.*, p. 59-60.

<sup>75</sup> See Aalto University, Tutkimuksen tiedote, *op.cit.* The compensation is based on the harm that is caused for participants and it has a legal background at Decree of the Ministry of Social Affairs and Health's statute (82/2011).

<sup>76</sup> TL. Beauchamp and JF. Childress, 2013, *op.cit.*, p. 150-152 and 202.

<sup>77</sup> B. Varkey, *op.cit.*, p. 18.

<sup>78</sup> TL. Beauchamp and JF. Childress, 2013, *op.cit.*, p. 153.

<sup>79</sup> TL. Beauchamp and JF. Childress, 2001, *op.cit.*, p. 117-118 and TL. Beauchamp and JF. Childress, 2013, *op.cit.*, p. 153.

<sup>80</sup> TL. Beauchamp and JF. Childress, 2013, *op.cit.*, p. 158-169.

<sup>81</sup> As was described in Chapter 4.1.1., research on a person without the capacity to consent is possible only if the additional conditions are met.



human being shall prevail over the sole interest of society or science.

The application form for Meliora states that the research will not cause harm to players, except for the time it takes to participate.<sup>82</sup> However, there might be a few risks associated with participation. Firstly, there is a risk to data protection, as personal data will be processed during the research. Although data privacy is widely considered in the research,<sup>83</sup> personal data will be transferred to the UK, the US and other EU countries. Data transfer to the UK is based on the acceptable level of data protection in the country, while transfer to the US, where data protection is not at the same level as in the EU, is based on a participant's consent.<sup>84</sup> Processing special categories of personal data<sup>85</sup> and providing access to research partners in a country with lower data protection standards could pose a risk, even though this risk may not be considerable. It is mentioned that transferred data does not include any information that could personally identify an individual, but it should be noted that participants may not have the option to deny the transfer of their data to other countries.<sup>86</sup> Secondly, processing data even in Finland can also pose risks of harmful consequences, and thus data protection must be carefully managed throughout the whole research.

As was discussed in Chapter 4.1.1., harm is related to autonomy. While it may be impossible

to define all potential harms or even define whether the research group should be more knowledgeable about those, the research group has identified some concrete risks and taken restrictive measures. For example, if a participant experiences side effects, they must stop playing Meliora and report the side effects to the researchers. In addition, participation is restricted for addicted players,<sup>87</sup> and each player is limited to a maximum of 90 minutes of gameplay per day.<sup>88</sup> These measures aim to prevent harm and ensure the safety of all participants.

However, it should be noted that depressed or addicted participants may not be able to identify all addiction symptoms and may face greater risks as a result. There is a lot of participant's consideration when weighing up incapacitation or addiction to digital games. Additionally, harm and risks may differ for both mentally and physically healthy and unhealthy individuals. Therefore, it is important to carefully consider whether the potential harm and risks are tiny enough to be acceptable under the principle of nonmaleficence and the Oviedo Convention. Finally, it is worth noting the same restrictive measures taken during the research must also be implemented when Meliora is ready for public use. This will help to ensure that the game remains safe and does not cause any unexpected harm.

Additionally, there is an issue concerning beneficence. While the research may have the potential to help with depression, there is no guarantee of any positive medical effects for participants.<sup>89</sup> In fact, the previous version of Meliora was not as effective at improving mental

<sup>82</sup> Aalto University, Rekrytointi-ilmoitus, *op.cit.*

<sup>83</sup> Aalto University, Tutkimuksen tiedote, *op.cit.*

<sup>84</sup> Aalto University, Tutkimuksen tiedote, *op.cit.*

<sup>85</sup> See Article 9 of the GDPR. Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (GDPR).

<sup>86</sup> See Aalto University, Tutkimuksen tiedote, *op.cit.*

<sup>87</sup> See Aalto University, Tutkimuksen tiedote, *op.cit.*

<sup>88</sup> See Aalto University, Tutkimuksen tiedote, *op.cit.*

<sup>89</sup> See Aalto University, Tutkimuksen tiedote, *op.cit.*

health as traditional methods. Therefore, beneficence may not be realized in every individual case, and some harm could be caused during the study. Consequently, the potential medical benefits to research subjects are not intended to be greater than the potential risks or harm.

However, the research may still be justifiable with utilitarian arguments,<sup>90</sup> and scientific benefit is also an acceptable reason to consider the relationship between benefits and harms. In the case of Meliora, the game is expected to benefit depressed people in the future and therefore, the research is going to have a utilitarian outcome. Nevertheless, when treatment does not directly benefit a participant, the potential harm or bother should be sole tiny.<sup>91</sup>

To determine whether the utilitarian argument is justifiable in the Meliora research, all possible side effects and other harms should be appraised even more carefully to see if they are tiny enough. The primary concerns are the risk of addiction and data privacy during the research, which must be weighed against the positive effects of gaming.

### 4.3. Justice

The formal principle of justice requires that equal individuals must be treated equally, and unequal individuals must be treated unequally.<sup>92</sup> Justice treatment of a person should be fair, equitable, and appropriate.<sup>93</sup> The legislation also supports justice. According to 1 Article of the Oviedo Convention, parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. Article 11 prohibits any form of discrimination against a person on grounds of his or her genetic heritage.

In the case of Meliora, the greatest challenge to justice arises from the fact that not all individuals have an equal opportunity to participate in testing. For example, certain age groups are restricted from the research. When research does not extend to certain people, it might not be safe to play Meliora after the research either. Therefore, some groups do not have access to this new form of treatment, which could cause issues with justification, especially in restrictive cases that cannot be justified with protection.<sup>94</sup> Additionally, the costs and access to treatment might cause issues when the game is

<sup>90</sup> See about utilian theories and concept of utility TL. Beauchamp and JF. Childress, 2013, *opt.cit.*, p. 355-361.

<sup>91</sup> HE 229/1998, *op.cit.*, p. 6.

<sup>92</sup> TL. Beauchamp and JF. Childress, 2013, *op.cit.*, p. 250-252.

<sup>93</sup> B. Varkey, *op.cit.*, p. 20.

<sup>94</sup> Additionally, for example older adults are usually underrepresented in clinical trials which might cause more ethical issues. See Forsat N, Palmowski A, Palmowski Y, Boers M, Buttgerit F. Recruitment and Retention of Older People in Clinical Research: A Systematic Literature Review. *Journal of the American Geriatrics Society* 2020, 68: 2955-2963. Available at: <https://doi.org/10.1111/jgs.16875>.

ready and therefore, they must be outweighed during and after the research.

## 5. Summary

This article examined legal and bioethical issues relating to the research on depressed people in the video game industry. The main issues identified in this article are related to depressed and addicted participants and their capability to give informed consent. These participants may also be more vulnerable to potential harms and risks, which can vary depending on the individual. Therefore, the potential risks and harms may also be different for, for example, healthy versus unhealthy

individuals. In addition, the research may not provide any benefit to a participant, which can create issues with beneficence, particularly when considering individuals with diminished autonomy. Finally, the exclusion of certain groups from the research may raise some concerns related to the principle of justice.

Overall, the issues discussed in the article are specific to the case of *Meliora*, but they may also have relevance in similar studies in the future. All research involving depressed individuals must be conducted with careful attention to legal and ethical considerations to uphold the principles of bioethics and relevant regulations. Ensuring the protection of vulnerable research subjects is essential.