Exploratory Psychometric Validation and Efficacy Assessment Study of Social Phobia Treatment based on Augmented and Virtual Reality Serious Games and Biofeedback

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“Without deviation from the norm, progress is not possible.”

Frank Zappa
Acknowledgements

I would like to express my sincere gratitude to Prof. Hugo Ferreira, for awakening my inner will to learn and constantly challenge myself. Thank you for the random (but in quite pinpointed times) pep-talks, for believing in my potential and, of course, all the tips and lessons (all the way from the sandwich complement strategy to the “eat my dust” motto). More than a supervisor, a mentor and an inspiration. A special thanks to my other supervisor, Prof. Beatriz Carmo for the support and patience throughout this process that ended up taking longer than the predicted one-year period. To Prof. Ana Paula Cláudio, thank you for the unofficial yet kind and valuable supervision (those improvised tablecloths worked wonders).

Conducting an experimental research is extremely challenging as it is highly dependent on participant engagement and I want to thank every single one of the 156 kind individuals that contributed to my dissertation thesis.

The psychiatric department’s team of Hospital de Beja, in particular Dr. Ana Matos Pires and Dr. Maria Suárez, was instrumental in defining the path of my research, from the initial conceptualization steps to the implementation. For this, I am extremely grateful. A special thanks to all the social phobia patients that partook in the study, your contribution was key.

To all the professors from the Institute of Biophysics and Biomedical Engineering, namely Nuno Matela and Alexandre Andrade, my sincere thanks for all the knowledge you shared with me and my colleagues, throughout the years. You are the main reason why we are passionate about seizing the opportunities to apply our knowledge to solve real life healthcare demands.

Thank you to the team behind NEVARO, both the initial group that helped launch the idea, Silvestre Piedade and Rafael Ramos (specially Rafael, for contributing for the first phase of this work), and the current team that blindly accepted facing the unpredictable entrepreneurial journey, André Manso and Miguel Lopes. Not to mention our neighbour-startup, EmotAI, and specially Carlos Moreira for the technical support and allowing me to resort to their self-built original headband for my work.

I would like, however, to give a special emphasis to Francisca Canais: a fortunate sheer coincidence joined us and, since day one, an unstoppable complementary duo was formed and without which neither this thesis nor the remaining project would be a reality.

I could not finish my acknowledgments without expressing my very great appreciation to all my friends and family, for the crucial support while embracing the adventurous risky choice of creating something from scratch and bringing it to life.
Resumo

Com o tamanho de aproximadamente dois punhos fechados e a aparência de uma enorme noz, o cérebro humano possui um poder inigualável, sendo um dos órgãos mais complexos e importantes do corpo humano. Tem a capacidade de um grande computador, capaz de receber e processar informação para depois enviar mensagens como resposta, e ainda assim é capaz de diferenciar a inteligência humana da de uma máquina – capacitando a espécie humana para muito mais, como é o caso particular dos pensamentos, sentimentos e emoções.

No entanto, apesar das suas impressionantes capacidades, o cérebro também é extremamente frágil. De acordo com a Organização Mundial de Saúde, 1 em cada 4 pessoas em todo o mundo irá sofrer de uma determinada doença mental ou neurológica, nalgum ponto das suas vidas. Adicionalmente, doenças do foro mental estão entre as principais causas de incapacidade a nível mundial, visto que afetam atualmente cerca de 450 milhões de pessoas, das quais 300 milhões foram apanhadas pelo maior flagelo da mente do milénio: ansiedade e as doenças que dela derivam.

Nos dias que correm, os métodos tradicionais de tratamento de patologias ansiogênicas, nomeadamente fobias, são de uma forma geral insatisfatórios, visto que tipicamente dependem de medicação, não possuem métricas objetivas nem existe uma continuidade casa/clínica. Na União Europeia, cerca de 83 milhões de pessoas sofrem de fobias. A patologia fóbica representa o grupo de perturbações de ansiedade com origem apenas, ou predominantemente, em determinadas situações bem definidas e que não representam qualquer perigo: tipicamente um medo persistente e excessivo de um objeto ou situação. Existem três tipos de fobias: fobias específicas, fobia social e agorafobia – sendo a fobia social a mais predominante.

No entanto, os métodos tradicionais de tratamento, que incluem a medicação, a terapia cognitivo-comportamental e a dessensibilização sistemática, possuem bastante limitações. Por um lado, a medicação tem uma atuação relativamente rápida, porém não resolve a raiz do problema e origina tipicamente efeitos secundários fortes e prolongados no tempo. Os métodos terapêuticos, mais seguros e com maior potencial, necessitam de longos períodos de tempo para que se começem a ver os primeiros resultados e, como tal, exigem um elevado compromisso e dedicação por parte do paciente, de tal forma que nem toda a gente é capaz de levar estes tipos de tratamento até ao fim. Adicionalmente, encontram-se com frequência geograficamente distribuídos de forma assimétrica e são ainda objeto de grande estigma e tabu.

Por outro lado, outra lacuna inerente à abordagem terapêutica em questão é a falta de métricas objetivas que quantifiquem o estado do paciente e o progresso do tratamento, visto que estão inteiramente dependentes da autoavaliação subjetiva da severidade do que sentem os próprios pacientes, bem como a análise, também esta subjetiva, por parte do terapeuta. Ora, este carácter subjetivo leva a uma eficácia de tratamentos muito variável, tornando estes métodos tradicionais muito pouco fiáveis.

O presente trabalho de dissertação focou-se na conceptualização, implementação e teste da eficácia de um mecanismo psicoterapêutico digitalizado, que combina jogos sérios com biofeedback para melhorar o tratamento da fobia social. Jogo sério é a designação dada a experiências gamificadas desenhadas para entreter o jogador, enquanto o educam, treinam ou induzem a alteração de comportamentos, não tendo o entretenimento como objetivo central. A aplicação desta técnica no campo da saúde tem vindo a ser comprovada como uma mais valia, incentivando o envolvimento ativo e dinâmico do paciente. No que diz respeito ao biofeedback, este consiste em protocolos de
condicionamento que visam manipular sistemas corporais, arbitrariamente, isto é, treino comportamental através da monitorização de processos fisiológicos específicos.

Assim, a abordagem idealizada pretende colmatar as lacunas da técnica de dessensibilização sistemática, recorrendo a jogos sérios para facilitar a recriação do ambiente de exposição fóbica em qualquer lugar e de forma controlada, motivar o paciente ao longo do seu tratamento, personalizar a sua jornada através do biofeedback e, recorrendo aos sinais fisiológicos utilizados para o esse feedback, monitorizar/quantificar objetivamente o progresso do tratamento.

Para tal, o estudo realizado nesta dissertação foi dividido em duas grandes fases. Primeiramente, foi concebido um método para classificação emocional, através da análise da atividade fisiológica usando Eletroencefalografia (EEG) e Fotopletismografia (PPG), experienciada aquando da visualização de 7 clips de vídeo que suscitam diferentes emoções. Para a validação desses clips, 100 sujeitos saudáveis foram submetidos à experiência e foram avaliadas as emoções sentidas, reportadas pelos próprios. Posteriormente, os vídeos mais eficazes para suscitar cada emoção foram selecionados e o protocolo repetiu-se para 25 novos sujeitos saudáveis e ambas as respostas relatadas e fisiológicas foram monitorizadas. A partir da informação recolhida, retiraram-se várias conclusões úteis para a próxima fase do estudo: relativamente à definição dos requisitos para seleção dos participantes (género, mão dominante), bem como à obtenção do biomarcador da ansiedade baseado nas métricas fisiológicas exploradas.

Em conjunto com a equipa psiquiátrica do Hospital de Beja, selecionaram-se 5 doentes masculinos e destros, com idades compreendidas entre os 26 e 58 anos, para participarem no estudo, sendo divididos em dois grupos: o experimental (3) que participou num total de 8 sessões, e o de controlo (2) que não teve qualquer tipo de interação com a investigadora, sendo que a informação necessária foi transmitida pelo seu médico psiquiatra. As duas primeiras sessões dedicaram-se às apresentações e a última serviu de follow-up para avaliar o progresso do tratamento. Ao longo das 5 sessões restantes, foram aplicados os jogos sérios (com Realidade Aumentada (AR) para a terapia por exposição e com Realidade Virtual (VR) para meditação imersiva) e a avaliação emocional, através dos dados fisiológicos de EEG e PPG e do conhecimento adquirido da fase anterior, permitindo a execução de um biofeedback manual, controlando a intensidade da exposição ao estímulo fóbico. Adicionalmente, os participantes também responderam a questionários universais para avaliar os níveis de ansiedade e de fobia social, de qualidade de vida e a experiência de jogo: Beck Anxiety Inventory (BAI); Liebowitz Social Anxiety Scale (LSAS); World Health Organization Quality of Life (WHOQOL-Bref); and Game Experience Questionnaire (GEQ), respetivamente.

Os resultados do grupo experimental relativamente ao grupo de controlo demonstram um decréscimo nas pontuações do BAI 6.06 vezes mais acentuado, um decréscimo nas da LSAS 4.57 vezes mais acentuado e um aumento do domínio das relações sociais da WHOQOL 4.24 vezes mais acentuado. Os jogos sérios foram validados através do GEQ, tanto o AR para estimulação fóbica gradual como VR para relaxamento e recuperação do estado desconfortável suscitado pela referida estimulação. Por fim, as métricas fisiológicas também confirmam tais conclusões, dado que se verificam diferenças significativas entre as tarefas com propósitos distintos.

Em particular, o presente estudo exploratório serviu como base para testar a usabilidade e recetividade da solução inovadora, bem como aferir o seu potencial e eficácia. Contudo, os resultados devem ser considerados à luz de algumas limitações, nomeadamente no que diz respeito à amostra populacional. Próximos passos para o projeto passam pela otimização dos jogos, tanto a nível gráfico, como da robustez e autonomia dos algoritmos de biofeedback. Posteriormente, uma prova de conceito com um grupo de pacientes de dimensão significativa para se retirarem as devidas conclusões e etapas
consequentes para a obtenção de comprovação/certificação clínica. Uma vez clinicamente comprovado, será possível usufruir do potencial da técnica para translação de parte da terapia para fora do ambiente clínico/hospitalar, tornando todo o processo de tratamento mais expedito e acessível.

Em suma, o principal objetivo de desenvolver uma solução de jogos sérios para tratamento de fobia social, centrada no doente, foi alcançado e o estudo sugere a eficácia da aplicação da mesma.

**Palavras-chave:** Fobia Social, Jogos Sérios, Classificador de Emoções, Biomarcador de Ansiedade.
Abstract

Nowadays, traditional anxiety treatment methods, namely for phobias, are overall underperforming as they typically rely on medication, and lack objective metrics and clinical/home treatment continuity. In the European Union alone, there are over 83 million people suffering from phobias, access to treatment methods is geographically asymmetrically distributed, and patients are still object of a lot of stigma and taboo. The present dissertation work focuses on conceptualizing, implementing and testing the efficacy of a digitalized psychotherapeutic approach, combining serious gaming and biofeedback for improving the treatment of one of the most common mental health disorders: social phobia.

To do so, the study was divided in two major phases. First, an emotion classifying method was conceived, through the analysis of Electroencephalography (EEG) and Photoplethysmography (PPG) signal collected whilst healthy subjects were watching a set of 7 emotion-eliciting videos excerpts. To validate the videos, 100 healthy subjects underwent the experiment and self-reported the emotions perceived. Subsequently, the most effective video on eliciting each emotion was selected and the protocol was extended to 25 new healthy subjects, and both self-reported and physiological responses were monitored. From the information collected, conclusions were retrieved for the next phase: defining participant selection requirements (genre, dominant hand) as well as obtaining an anxiety biomarker based on the explored physiological metrics.

Together with the psychiatric team of the Hospital de Beja, 5 male right-handed social phobia patients, aged from 26 to 58 years old, were selected to partake in the study, divided in two groups: the experimental group (3) that participated in a total of 8 sessions, and the control group (2) that had no interaction with the researcher and whose relevant information was transmitted by their physician. The first two sessions were dedicated to presentations and acquaintance with the research team, and the last served as a follow-up moment to assess the treatment progress. During the remaining 5 sessions, the Serious Gaming technique was applied (Augmented Reality (AR) to perform exposure therapy and Virtual Reality (VR) for immersive meditation) and the physiological emotion assessment, through EEG and PPG knowledge acquired in the previous phase, to perform a manual biofeedback, adapting the intensity of the exposure to the phobic stimuli. Additionally, participants also filled out self-reported questionnaires to assess anxiety and social phobia levels, quality-of-life and the gaming experience: Beck Anxiety Inventory (BAI), Liebowitz Social Anxiety Scale (LSAS), World Health Organization Quality of Life (WHOQOL-Bref) and Game Experience Questionnaire (GEQ), respectively.

Results demonstrated a decrease on BAI scores 6.06 times more accentuated in the experimental against the control group, a decrease 4.57 times more accentuated on the overall LSAS traces and an increase 4.24 times more accentuated on the WHOQOL domain of social relationships. The serious games were validated through GEQ, both the AR for stimulating uncomfortable states that trigger social phobia, and the VR for inducing the relaxing state to recover from the previous phobic-stimulating experience. Lastly, the physiological features also confirm said conclusions, since there were significant differences identified between tasks with the described separate purposes.

Notably, the present exploratory study served as the basis for testing the usability and receptivity of such an innovative solution, as well as assessing its potential efficacy. There is, however, the need to have an increased sample size under testing to confirm the obtained results. All in all, the primary objective of the developing a patient-oriented serious game solution for social phobia treatment was achieved and the study suggests the effectiveness of its application.

Keywords: Social Phobia, Serious Games, Emotion Classifier, Anxiety Biomarker.
“Comunicação de Invenção” / Reporting of Invention

Given the innovative trait of the technology conceptualized and developed in the context of the present dissertation work, the invention was formally communicated to the Faculty of Sciences of the University of Lisbon. Documentation provided included the detailed description of the technology, its state-of-the-art and competitive landscape, the specific features of innovation and the inventors responsible, as well as the divulgence done thus far. In the moment of submission, the invention was classified as a TRL 4, Small Scale Prototype, and had not yet been tested with the social phobia patients in the second phase of the study, at the Hospital de Beja.

The Faculty’s responsible committee deliberated on the relevance of having an active presence on closely accompanying the project as well as on further steps of technology protection. The decision was favourable, although it was suggested to wait until experimental results were obtained to review the situation and clarify any further action to be taken. The official decision statement can be consulted in Annex I.
# Contents

Acknowledgements .................................................................................................................. v
Resumo ...................................................................................................................................... vii
Abstract ................................................................................................................................... xi
“Comunicação de Invenção” / Reporting of Invention ................................................................ xiii
Contents ..................................................................................................................................... xv
List of Figures ........................................................................................................................... xvii
List of Tables .............................................................................................................................. xix
List of Abbreviations .................................................................................................................. xxi
Motivation ................................................................................................................................... 1
Context and Structure of the Dissertation .................................................................................. 3
1. Theoretical Background ......................................................................................................... 5
   1.1. Nervous System .............................................................................................................. 5
       1.1.1. Structures of Interest ............................................................................................. 6
       1.1.2. Limbic System and Emotions .............................................................................. 7
       1.1.3. Emotional Process ............................................................................................... 9
   1.2. Anxiety .......................................................................................................................... 10
   1.3. Phobias ......................................................................................................................... 11
   1.4. Treatment Methods ...................................................................................................... 12
   1.5. Serious Games ............................................................................................................. 14
       1.5.1. Virtual Reality ..................................................................................................... 14
       1.5.2. Augmented Reality ............................................................................................ 15
       1.5.3. ARET vs VRET .................................................................................................. 16
   1.6. Physiological Activity Monitoring and Biofeedback ...................................................... 16
       1.6.1. Brain Activity and Electroencephalography ....................................................... 17
       1.6.2. Heart Activity and Photoplethysmography ........................................................... 19
   1.7. Emotion models ........................................................................................................... 20
   1.8. Proposed solution ........................................................................................................ 22
2. Methodology ......................................................................................................................... 23
   2.1. Phases of the study ....................................................................................................... 23
   2.2. First Phase: Assessment of Physiological Data while Watching Emotion - Eliciting Videos for Extraction of Emotion Classifying Biomarkers. .................................................. 23
       2.2.1. Outline and Aim ................................................................................................. 23
2.2.2. Materials Required ................................................................. 24
2.2.3. Participants ................................................................. 26
2.2.4. Procedure ................................................................. 27
2.2.5. Risk Considerations ......................................................... 28
2.2.6. Performance Metrics ....................................................... 28
2.2.7. Data Analysis ................................................................. 29
2.3. Second Phase: Efficacy Assessment of AR/VR and Biofeedback Applied to Social Phobia Treatment and Immersive Meditation ................................................................. 30
   2.3.1. Outline and Aim .......................................................... 30
   2.3.2. Materials Required ....................................................... 31
   2.3.2.1. Games for Exposure Therapy – ARET/VRET ................. 35
   2.3.3. Participants ................................................................. 39
   2.3.4. Procedure ................................................................. 41
   2.3.5. Risk Considerations ....................................................... 42
   2.3.6. Performance Metrics ....................................................... 43
   2.3.7. Data Analysis ................................................................. 43
3. Results .............................................................................. 45
   3.1. Does the video set elicit differentiated emotional states? If so, which videos yield strongest levels of arousal, positive and negative traits? .................................................. 45
   3.2. Are there any gender differences on how emotional states are perceived? .......... 49
   3.3. Do the physiological data significantly reflect the differentiated emotional states elicited? ........................................................................................................ 50
   3.4. Are there any differences on how emotions are perceived, among healthy and phobic subjects? ......................................................................................... 53
   3.5. Does the introduction of the serious gaming component have a significant influence on the treatment? How do experimental and control groups differ? ............... 54
   3.6. Are the AR/VR games validated? Are there significant differences between both skills? 59
   3.7. How do physiological data vary among different tasks? ........................................ 61
4. Discussion ........................................................................... 65
5. Conclusion & Future Work ......................................................... 71
References/ Bibliography ................................................................. 73
ANNEX I .................................................................................... 81
ANNEX II .................................................................................. 83
ANNEX III ............................................................................... 85
ANNEX IV ............................................................................... 91
Motivation

With the size of roughly two clenched fists and the looks of a large walnut, the human brain has peerless power, being one of the central most complex organs in the human body. It has the capacity of a big computer, processing received information to then send back messages as response, and yet is also able to outstand the human intelligence from the machine’s – enabling so much more, as is the particular case of thoughts, feelings and emotions [1].

In fact, physiologically, all information circulation is based on action potentials, neurotransmitters, synapsis and countless chemical reactions. Emotions, however, are more complex than that: defined as a collection of responses generated from one region to another, both brain-body or brain-brain, resulting in changes within body processes and particular brain sectors, which can be designated as emotional states [2]. Therefore, in order to understand the emotion, one must focus on identifying the stimuli working as the trigger, as well as the externalized responses. On the other hand, to characterize and measure emotions in a less self-reported way, objective methods are required. Studies have shown evidence of different brain-wave behaviour, depending on the emotion experienced [3][4][5].

Unfortunately, despite its astonishing aptitudes, the brain can be extremely fragile too. According to the World Health Organization, every one out of four people worldwide are expected to suffer, at some point in their lives, from some neurological/mental illness. Furthermore, mental disorders are among the leading causes of disability worldwide, since it is currently affecting 450 million people, of which 300 million are being caught by the greatest mind thief of this millennium: anxiety and its related disorders [6]. Notwithstanding, great examples of anxiety related disorders are phobias, affecting 83 million people in the European Union alone, and particularly relevant for the present study.

The aim of this dissertation is to research, develop, implement and test the efficacy of a novel digital therapy solution for the treatment of anxiety related disorders, namely phobias, through innovative serious gaming techniques.

Efficacy will be assessed through subjective measures, namely questionnaires, and objective measures, i.e. psychophysiological metrics. When proven effective, this technique can be applied to bridge the loopholes of the traditional methods and expedite the treatment itself, turning it into a process as objective as possible.

Coupling that with the possibility to impact people directly, innovate and eventually create a real product out of it, a certain entrepreneurial determination has awakened, which is fuelling the pursuit of the unconventional science-to-business translational path.
Context and Structure of the Dissertation

To fulfil this dissertation’s purpose of validating and assessing the efficacy of a novel social phobia treatment solution, preliminary research was needed. Hence it was composed of two main phases: the first focused on the extraction of emotion classifying biomarkers through the assessment of the physiological response, and secondly the exploratory assessment of the proposed solution, resorting to standard self-reported questionnaires and the metrics defined in the previous phase.

The initial experimental set made use of emotion-eliciting video excerpts and required the involvement of voluntary participants to obtain appropriate results. The sample of subjects obtained was recruited in the Faculty of Sciences of the University of Lisbon and tests were conducted at Instituto de Biofísica e Engenharia Biomédica (IBEB). On the other hand, the social phobia treatment proposed resorts to an AR serious game for a controlled safe exposure to the fear trigger as well as a VR immersive meditation inducing experience. In this segment of the study, the participants enrolled were patients beginning psychiatric treatment at the Hospital de Beja, and therefore all experimental testing was conducted in in-person sessions at the psychiatric department of said hospital.

The present dissertation work is divided into five chapters. In Chapter 1, the theoretical concepts are thoroughly explained to integrate the reader within the context of this thesis. Featured is a literature review on core concepts of the nervous system and its functioning, anxiogenic diseases and an emphasis is given to phobias, along with a state-of-the-art analysis of the current treatment methods and the approach chosen, as well as of the physiological activity monitoring techniques. Chapter 2 addresses the materials and methodology used throughout the whole study: the two main phases are described in detail, namely conceptualization, implementation and results’ analysis processes, as well as the participant selection, experimental protocols and risk considerations. In Chapter 3, the results obtained are exhibited, while the 4th Chapter presents their discussion, along with the limitations of the investigation procedures and outcomes. Lastly, Chapter 5 provides the main conclusions drawn from the research conducted within this thesis, along with future work steps and the overall final remarks.
References


ANNEX I

Figure I.1: Official statement on the decision of Faculdade de Ciências da Universidade de Lisboa regarding the "Comunicação de Invenção"/Report of Invention of the work developed in this dissertation project.
Figure II.1: Official statement of approval from the Ethics Committee of the Faculdade de Ciências da Universidade de Lisboa regarding the experimental study of the First Phase of the present dissertation project.
ANNEX III

ESCALA DE ANSIEDADE DE BECK - BAI

Nome: ___________________________________________ Data: __/__/____

Abaixo está uma lista de sintomas comuns de ansiedade. Por favor, leia cuidadosamente cada item da lista. Identifique o quanto tem sido incomodado por cada sintoma durante a última semana, incluindo hoje, colocando um “x” no espaço correspondente, na mesma linha de cada sintoma.

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<td>3. Tremores nas pernas</td>
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<td>4. Incapaz de relaxar</td>
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<td>9. Aterrorizado</td>
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<td>10. Nervoso</td>
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<td>14. Medo de perder o controlo</td>
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<td>15. Dificuldade de respirar</td>
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<td>19. Sensação de desmaio</td>
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<td>20. Rosto avermelhado</td>
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<td>21. Suor (não devido ao calor)</td>
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Figure III.1: Beck Anxiety Inventory used for the self-reported evaluation of the patients’ anxiety levels: validated Portuguese version.
Figure 38III.2: Liebowitz Social Anxiety Scale used for the self-reported evaluation of the patients’ social phobia levels: adaptation of the validated Portuguese version.
Figure III.3: Game Experience Questionnaire – Core Module used for the self-reported evaluation of the patients’ experience throughout the game: inhouse translation to Portuguese.
Figure III.4: Game Experience Questionnaire – Modules of Social Presence and Post Game used for the self-reported evaluation of the patients’ social presence perception and experience after the game: inhouse translation to Portuguese.
Figure III.5: World Health Organization Quality of Life used for the self-reported evaluation of the quality of life: established Portuguese version.
ANNEX IV

EXTRATO DA ACTA DA REUNIÃO N.º 02/2019 DA COMISSÃO DE ÉTICA HOMOLOGADA PELO CONSELHO DE ADMINISTRAÇÃO EM 05.02.2019 (Ata nº 07, Ponto 4.1)

Aos quatro dias do mês de fevereiro de dois mil e dezanove, pelas catorze horas e trinta minutos, na Sala João Paradela do Serviço de Psiquiatria e Saúde Mental, reuniu a Comissão de Ética da ULSBA, estando presentes: Ana Matos Pires, Assisente Graduado-Sénior de Psiquiatria, Diretora do Serviço de Psiquiatria e Presidente desta Comissão, Carla Alexandra Bicas Pereira Lourenço, Técnica Superior de Serviço Social, José Maria Alfonso Coelho, Capelão e Coordenador do Serviço de Assistência Espiritual e Religiosa, Sandra Manuela Figueira Hélio Serrano, Enfermeira do Gabinete de Promoção e Garantia da Qualidade, Sara Isabel Veiga Martins, Assisente de Medicina Geral e Familiar, e Silvia Edgar Âurelio Lamprea Guerreiro, Farmacêutica. Não pôde estar presente Aida Maria Matos Pardal, Enfermeira, que justificou a sua falta.

PONTO SETE – EDOC/2019/5006 – Estudo Comparativo de eficácia da Ação de realidade virtual /Aumentada e Neurofeedback ao tratamento de fobias, a realizar pelos Engenheiros Biomédicos Rita Maçãsoro, Francisco Canais e Hugo Alexandre Ferreira.

A Comissão de Ética emitiu parecer favorável. A Presidente desta Comissão não votou por ser colaboradora neste estudo.

Beja, 13 de fevereiro

A Presidente da Comissão de Ética

[Assinatura]

Ana Matos Pires

Figure IV.1: Official statement of approval from the Ethics Committee of Unidade Local de Saúde do Baixo Alentejo regarding the experimental study of the Second Phase of the present dissertation project.