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Abstract

This report provides a detailed description on the phase II of the pilot experiments. Within this phase, the MAMEM platform was given to potential users to use at their homes for a duration of one month in which their usage pattern was monitored. This report describes: (1) the study protocol (2) Three sets of comprehensive results and analyses of experiments conducted in three clinical cohorts: people with Neuromuscular diseases, people with Parkinson's disease and people with a spinal cord injury (3) A discussion of the results, conclusions and recommendations on future use of the platform.

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Executive Summary

The goal of the MAMEM project is to provide a tool for disabled people that can enable them to integrate back into society, by allowing them a better use of computers and thus a better option to participate in social networks. To do this, a novel way to control computers using eye-gaze was developed by the technological partners in the project. To assess whether this novel way can indeed provide a better operating solution, it must be evaluated by the potential users.

The Phase II trials of the MAMEM project was conducted at M34-38 of the project and designed to evaluate the MAMEM platform in an uncontrolled environment – potential users' homes and aimed to assess the impact of the new platform on the core target variable of the project, which is to foster social integration by allowing to author and manage multimedia content. This phase was conducted following an interim period, in which the platform was optimized and finalized in light of the insights that were made following Phase I.

In the trials, 10 participants from each clinical cohort of the project – people with neuromuscular diseases, people with Parkinson's disease and people with a spinal cord injury, were provided with the MAMEM platform to use at their homes. In the first visit (i.e. the first day of usage), they were trained on how to use the platform. In the one-month period they could use the platform as much as they wanted, and for any need. In the final visit (i.e. last day of usage), the platform was removed from their homes and questionnaires were administered to evaluate their personal perspective regarding the platform. During the one month, their online activities and public social activities were monitored. The total usage of the system and the users' public activity in online social networks served as the primary outcome measures.

The apparatus of Phase II trials included a standard laptop computer with 'GazeTheWeb', i.e., the tool that was developed within the MAMEM platform that enables surfing the internet with the use of the eyes - installed on it, together with an eye tracking system. In selected subjects, the apparatus also included an EEG and a GSR device that were used in collaboration with the experimenter during his first visit to operate the multi-modal interfaces of error-aware gaze-based keyboard and a hands-free version of the Tetris game (MM-Tetris).

Phase II successfully met its objective in that it provided potential users sufficient time to test the system and its primary and secondary outcomes were defined in such a way that they enabled to assess the usage of the MAMEM technology. The trials provided evidence that the MAMEM platform can indeed serve as an assistive device for some disabled people. However, the usage patterns varied due to various subjective measures of user impairment stage, preferences, prior interaction experience, performance and accuracy. We highlighted some of these measures as part of trial outcome in quantitative and qualitative analysis.

Abbreviations and Acronyms

BCI	Brain Computer Interface
EEG	ElectroEncephaloGram
GSR	Galvanic Skin Response
NMD	Neuromuscular Disorders
PD	Parkinson Disease
SCI	Spinal Cord Injury

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1 Introduction

The goal of the MAMEM project is to provide a tool for disabled people that can enable them to integrate back into society, by allowing them a better use of computers and thus a better option to participate in social networks. To do this, a novel way to control computers using primarily their eye-gaze was developed by the technological partners in the project. To assess whether this novel way can indeed provide a better operating solution, it must be evaluated by the potential users. This is why clinical trials were incorporated in the project as part of the developing process.

The clinical trials had two objectives: (1) to assess the feasibility and usability of the system among the potential users, i.e. spinal cord injury (SCI), neuromuscular disorders (NMD) and Parkinson's disease (PD); (2) To test the ability of the platform to enhance the social communication activities of the patients in real-world conditions, i.e. the patient's homes.

Relevant to this evaluation part, the MAMEM project's milestones included: first, assessment of the clinical requirements of the platform by the potential users. This part was done in the early parts of the project and described in D6.1 and D6.2 [1,2]. Next, a protocol for clinical trials aimed to directly assess the feasibility and usability of the platform was created and described in D6.3 [3]. The protocol and informed consent forms of the clinical trials were approved by the local institutional ethical committees of each clinical site (see Appendix A.2). Finally, two-phase clinical trials were conducted with potential users from the three project cohorts.

The first phase of the clinical trials was conducted in M22-M24 of the project, was designed as a feasibility and usability study of the system among the potential users and able-bodied participants and targeted to assess the MAMEM platform in a controlled environment. In these trials, 18 able-bodied participants and 16 participants with neuromuscular diseases, Parkinson's disease and spinal cord injuries, arrived at the three clinical centres and tried the platform for a few hours. The findings of this phase are described in D6.4 [4] and were later used to provide insights about the feasibility of clinical cohorts to operate the system and ways to optimize the system in light of their experiences and performances.

The Phase II trials of the MAMEM project was conducted at M34-38 of the project and designed to evaluate the MAMEM platform in an uncontrolled environment – potential users' homes and aimed to assess the impact of the new platform on the core target variable of the project, which is to foster social integration by allowing to author and manage multimedia content. This phase was conducted following an interim period, in which the platform was optimized and finalized in light of the insights that were made following Phase I. In the trials, 10 participants from each clinical cohort of the project were given a laptop computer with the MAMEM platform installed on it, as well as an eye-tracker for a period of one month to use at their homes. In the first visit (i.e., first day of usage), they were trained on how to use the platform. In selected subjects, during the first visit two multi-modal

interfaces including an error-aware gaze-based keyboard and a hands-free version of Tetris (MM-Tetris) were tested in collaboration with the experimenter. In the following period of one month the subjects could use the platform as much as they wanted, and for any need. In the final visit (last day of usage), the platform was removed from their homes and questionnaires were administered to evaluate their personal perspective regarding the platform. During the one month, their online activities and public social activities were monitored. The total usage of the system and its usage in online social networks served as the primary outcome measures.

The apparatus of Phase II trials included a standard laptop computer with 'GazeTheWeb' - I.e., the tool that was developed within the MAMEM platform that enables surfing the internet with the use of the eyes - installed on it, together with an eye tracking system. In selected subjects, the apparatus also included an EEG and a GSR device that were used in collaboration with the experimenter during his first visit.

The following report describes the findings of Phase II of the trials in respect to the three clinical cohorts. Notice that he social inclusion related results of phase II are reported in D7.3.

2 METHODS OF THE PHASE II CLINICAL TRIALS

In the following sections we describe the methods of the Phase II of the clinical trials.

2.1 Participants

2.1.1 10 Participants with Neuromuscular Disorders (MDA Hellas)

In MDA Hellas, following the experience from the Phase I trials, only NMD patients with specific clinical characteristics to participate in Phase II were approached to. A total of 16 participants were interviewed and initially screened over the phone, according to the inclusion/exclusion criteria for the study. From the screened group of patients, 12 of them agreed to participate and were found to be suitable for the study. From the four that did not join the study, one reported that he already had an assistive device which he used and that it is working at a satisfactory level, and he did not believe that he would benefit from the MAMEM system. The other three have reported not having enough time to work on the MAMEM platform as much as they should. From the 12 successful candidates, 10 were selected to participate, while 2 agreed to be in the reserve list, in case of a participant's failure in the pre-test phase or in case of an early dropout.

Before the beginning of the trials, a pre-test was run on each of the potential participant's in order to check their ability to operate the eye-tracker and minimize the risk of dropping out due to this reason. Therefore, in 7 cases, an experimenter and a technician visited participants at their homes and in 3 cases, participants visited MDA Hellas offices to have the pre-test and made sure that they could operate the eye tracker using a simple five-minute operation task. In these pre-tests, all of the potential participants passed the test and could operate the eye-tracker effectively.

2.1.2 10 Participants with Parkinson's disease (AUTH)

Twenty computer literate patients with Parkinson's disease, fulfilling the inclusion/exclusion criteria for the MAMEM project, were interviewed during a regular visit at the Hospital Outpatient Clinic, as possible suitable candidates for the study. Eight patients refused to participate due to either lack of interest (6 participants) or inability to comply (2 participants). One participant who had participated successfully in Phase I of the clinical trials could not continue in Phase II trial, because in the meantime he developed a serious health problem that required frequent hospitalizations.

The remaining eleven patients performed very well in the pre-test trial, proving that they would be able to use the MAMEM platform at home. The first 10 were selected for the study and one remained in the reserve list. Just before the beginning of the Phase II trial, one of the participants was obliged to move out of town for family reasons and he was replaced by the reserve list patient.

2.1.3 10 Participants with a Spinal Cord Injury (Sheba)

A total of 20 participants were screened for the study over the phone. Out of these, 12 participants agreed to participate and were found to be suitable for the study. Out of the eight that did not, five SCI participants reported that they already have an assistive device

which they use to operate computers and that it is working at a satisfactory level so that they do not believe that they would benefit from the MAMEM platform. One SCI potential participant reported that he is religious and has no need to access the internet. Two participants were found suitable for the study, agreed to participate and signed an informed consent form, but later on decided to cancel their participation for their own reasons. From the 12 potential candidates, 10 were selected to participate, while 2 were kept on as reserves.

Since in Phase I of the clinical trials, two participants from the spinal cord cohort dropped out of the study due to inability to operate the eye-tracker, it was decided before the beginning of the trials to pre-test each potential participant's ability to operate the eye-tracker in order to minimize the risk of dropping out due to this reason. Therefore, in almost all cases, an experimenter from each clinical site visited each of the participants at their homes before the kick-off of the one-month period and made sure that they could operate the eye-tracker using a simple five-minute operation task. In these pre-tests, only one potential participant from Sheba could not operate the eye-tracker. This participant was then replaced with one of the participants on the reserve list.

Continuing with the participants that could operate the eye-tracker, eventually, one participant dropped out from the study due to lack of motivation and lack of cooperation with the study personnel.

2.2 Apparatus

The apparatus of Phase II trials included a standard laptop computer with 'GazeTheWeb' installed on. The laptops were relatively new with i5 6th generation intel processors, 4 GB RAM and 240 GB SSD hard drives. For the gaze behaviour analysis, the MAMEM apparatus also included the myGaze[1] eye tracking system.

The MAMEM platform included the final version of 'GazeTheWeb' on each computer, in addition to supporting software for the trials. This supporting software included the TeamViewer application [8] which was for remote technical support if needed. In addition, the MAMEM platform included a built-in monitoring mechanism that recorded every action that the user performed with the system. This monitoring mechanism had a temporary 'turn-off' option for privacy reasons. As the default page of GazeTheWeb the MAMEM dashboard / Homepage was used (see D5.3 [6]) so as to inform the participants for their digital indicators of social integration. Another monitoring mechanism was the social tracker application which monitored the public activities of the participants in online social networks.

Moreover, in selected subjects (2 participants from the PD cohort and 3 participants from the NMD cohort) the apparatus also included the ENOBIO 8[2] EEG device and the Shimmer

[1] http://www.mygaze.com/

[2] https://www.neuroelectrics.com/products/enobio/enobio-8/

GSR sensor[3] that were setup (additionally to the eye-tracker) in collaboration with the experimenter so as to test MAMEM's multi-modal interfaces including the error-aware gaze-based keyboard and the hands-free version of Tetris (MM-Tetris).

For more information on the apparatus or the monitoring mechanism see the protocol in D6.4 [4].

2.3 Procedure

Access to the full details of the procedure that has been followed during Phase II trials can be obtained by going through the template of the Case Report File (CRF) that has been utilized by the experimenters to report on all data collected for each subject (see Appendix A.1).

2.3.1 GazeTheWeb Usage

Participation in the study was done in several stages. First, approximately one month before the installation of the system, the participants were contacted over the phone and received an explanation regarding the study. The Informed consent forms were then sent to them and a short pre-screening meeting was coordinated. The phone call also included the initiation of a social monitoring mechanism by asking the "Facebook", "Twitter" and "Google Plus" usernames from the participants, assuming that they had one, and entering them into a social tracker application that was created for the MAMEM project. Finally, the phone call included passing out some of the 'before-usage' questionnaires (see Appendix A.1, also see [7]).

In the pre-screening meeting, the ability to operate the eye-tracker was tested and, in some cases, the 'before-usage' questionnaires were passed out, in case they were not passed out over the phone. The pre-screening meeting was done in almost all cases, except in cases where the participants lived in remote locations, far from the clinical centre. In these cases, carrying out the pre-screening meeting would have been too resource and time-consuming. It was therefore decided that, in these cases, the risk of recruiting an unsuitable participant was worth taking.

In the next stage, the first visit of the trial in each participant's home took place. This visit consisted of several steps: First, the participant has signed an informed consent form. Then, the experimenter filled a demographic and clinical questionnaire, in case they were not done before, and a questionnaire that recapped the computer use habits of the participants. This questionnaire was built using parts of the questionnaire that was prepared for this purpose for the requirements assessment study that was performed early in the project. For more information on this, see D6.2 [2].

[3] http://www.shimmersensing.com/products/shimmer3-wireless-gsr-sensor

At this point, in case the participant had a Facebook account, his/her username was entered into the MAMEM Facebook developer's application as an additional social monitoring mechanism [5]. The next step was locating an appropriate operation station for the laptop, one that could enable the proper use of the eye-tracker. This meant that the laptop had to be positioned at a certain height and angle, which, for the cohorts that must use a wheelchair, meant that these participants were to be able to have sufficient room underneath the table or shelf while sitting on the chair. Once the operation station was located, the installation of the platform took place, including connecting all the devices as well as connecting the laptops to the local WIFI internet network. In case an appropriate location was not located (since the participants did not use a computer regularly and therefore did not need one), the participants were strongly urged to create one in the following days.

At this point, each participant was given an explanation on how to operate the system, including: how to turn it on and off, how to operate the 'GazeTheWeb' interface using their eyes, how to open pages, scroll in them and save them as bookmarks, how to use the 'GazeTheWeb' keyboard etc. This part took as long as needed. In addition, the participants were given a full and profound explanation about the GazeTheWeb built-in monitoring mechanism that records each of their action, and how to turn it off when they desire. Once this stage was complete, the participants were asked to perform the training games, unless they felt too exhausted to do so. In these cases, they were shown how to locate them and were asked to perform them in the next few days. The experimenter followed up on this.

In the 'technicalities' part of the visit, participants were notified regarding sites that promote social inclusion, they were suggested to visit them and were taught how to view their social activities on the 'GazeTheWeb' dashboard (i.e. MAMEM dashboard/ Home page). This dashboard was designed to provide the participants with their progress in accessing social sites from different categories and with their progress in the training games according to the persuasive design principals and user models that were formulated within the MAMEM project for this purpose. For more information on this see D5.3 [6]. In the end, the participants were explained how to be in contact with the study personnel in case they needed technical support, how to enable remote technical support using the TeamViewer application [8] and how to leave audio diary recordings using the windows 10 native "voice recorder" application.

In the last part of the visit, the participants were explained what was to come. Specifically, that two weeks later, the experimenter will perform the two weeks phone call, in which a short survey will be passed, and one month after the first visit the platform will be removed and final visit activities will take place, including clearing the computer from all of their personal private data and browsing history so that other participants can use it, or in the case of the final participants, so that the computers can be returned to the renting company

(or the owing partner) without the risk of violating participants' privacy, as people unrelated to the study could otherwise gain access to personal information.

Two weeks after the installation visit, an experimenter performed a phone call to the participants in which a short, structured questionnaire was performed. The questionnaire included three Likert style questions regarding the experience with the platform and two open questions, regarding technical difficulties and things that the study personnel can assist with. The questions were: (1) how satisfied are you using MAMEM, up to this point? (2) In comparison to the previous digital device, how satisfied are you with MAMEM? (3) Now that you have tried MAMEM for 2 weeks, how probable is it that you would recommend it to a person in your condition?

The final visit was carried out one month after the first visit (when possible - there were some deviations from this due to weekends, holiday and due to participants' own schedule conflicts). The last visits' activities included removing the system from the participants' homes, passing out the 'after-usage' questionnaires (see Appendix A.1, [7]) and dealing with questions and possible discomfort due to the removal of the system. The last part was done using a pre-prepared Questions-and-Answers manual prepared by the psychologists of the consortium, included into the CRF (see Appendix A.1) for that purpose.

2.3.2 Experience of Multi-Modal Interfaces

In selected subjects, during the first visit the ENOBIO 8 EEG device and the Shimmer GSR sensor were installed (additionally to the eye-tracker) in collaboration with the experimenter and a few hours were spent on testing MAMEM's multi-modal interfaces including the error-aware gaze-based keyboard and the hands-free version of Tetris (MM-Tetris).

During the MM-Tetris experiments participants were asked to perform a set of tasks in order to initially calibrate the system (i.e. build a personalised classification scheme) and later on to operate the system in an online mode for personal amusement. At the beginning of the experimental procedure the experimenter explained to the participant the protocol and its purpose. The followed protocol is divided into two major stages, the calibration and the testing. During the calibration stage we performed the data acquisition for the two employed modalities, namely EEG and GSR. We must underline here that although eye-tracking was also of paramount utility it was not active during the calibration stage since no gaze training data are required for the testing stage. After the EEG cap and the GSR device were set on the participant an SMR experiment (the typical provided by the OpenVibe software; refer to Appendix 8 – CRF Phase II) was initiated. During this SMR experiment the participant was asked to perform an imaginary fist clench, as if squeezing a soft ball, with either the left or the right hand. In order to dictate the type of the asked task (i.e. left or right fist) a visual indication was presented in the screen indicating the corresponding required action. After gathering the essential data for calibration (40 fist clenches of each type accompanied by the corresponding skin responses) and building a personalized

machine learning model that enabled the online SMR classification the testing stage could begin. At this point the participants were able to operate the MM-Tetris using their spontaneous and intentional physiological activity to affect various elements of the game. In the adopted MM-Tetris paradigm the EEG signal is exploited by means of sensorimotor rhythms in order to enable the rotation of tetriminos when they initially appear at the top of the screen. After the rotation-active period is over, the tetriminos start to fall and participant's gaze is used to denote the place that tetriminos will land. The falling speed was adjusted according to the participant's stress level, as it was calculated by the signals obtained from GSR.

Regarding the error-aware gaze-based keyboard, the recording protocol relied on a standard gaze-based keyboard paradigm that was implemented by an eye-tracker attached to a pc monitor. The gazing information, in the form of a densely sampled sequence of x-y coordinates corresponding to the eye trace on the screen, was registered simultaneously with the participant's brainwaves. The purpose of this experiment was to provide data where patterns in the physiological activity, of either brain or/and eyes, could be associated with the case of a typo (due to either the inaccuracy of the eye-tracker or a human mistake). In the study of event-related neurophysiological responses, the precise timing is of paramount importance. For this reason, the functionality of the gaze-based typesetting system had to be modified. Typical gaze-based keyboards use a visual indication to continuously inform the user about the gaze location. A visual key is registered, only, after the user has constantly gazed at it for a certain amount of time (i.e. dwell time). However, this visual feedback notifies the user on the typing result at arbitrary times and as such the ErrPs are not time-locked to the registration of the visual key. This option of continuous visual feedback was deactivated in our experimental setup in order to ensure that transient brain responses, time-locked to erroneous typesetting, would be elicited. It was only after a stared key had been typed (or, equivalently, gazed at for more than 0.5 seconds) that appeared as selected. In this way, the perception of a typo could be associated with a specific timestamp. In other words, the onset of a wrong selection was the trigger for an ErrP-response. Twenty sentences, were provided sequentially to the subjects with the instruction to type them with the adjusted gaze-based keyboard. The current sentence was not accessible to the subjects during the typesetting, hence they had to memorize it at the beginning of each attempt. This was motivated by the need to bring the subject closer to the natural way of typing, where one types spontaneously. The only difference with the regular typesetting mode was the instructions to the participant to refrain from using backspace button and ignore typos since we were interested in physiological events associated with error perception and not in those related to reaction. All sentences, had to be written using lower-case letters with a full stop at the end. Each session, which consisted of typing one sentence, was followed by a short-time break. In a similar fashion, the first stage of the experiment was required in order to calibrate the system. After the calibration stage was

over and a classification model was trained by both brain and eye-related activity the testing stage followed. Participants were free to type in a browsing session were their presumably erroneous typing actions were auto-detected and corrected by the error-aware system.

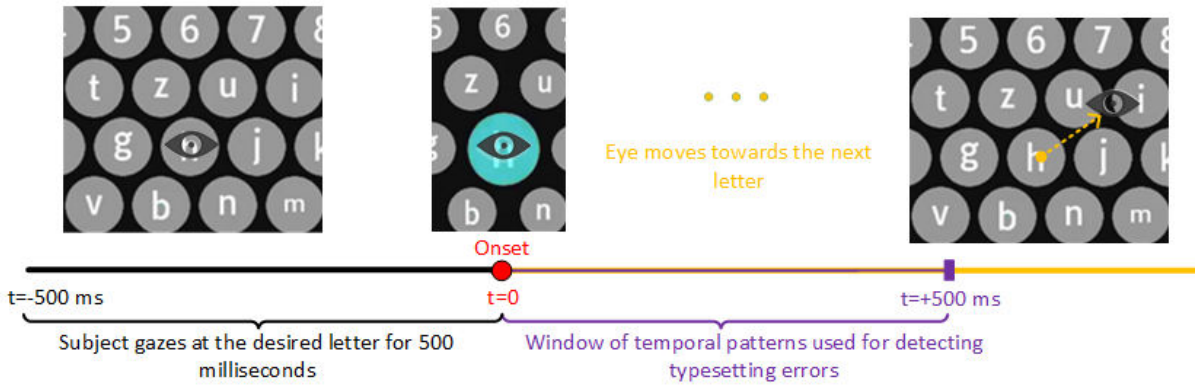

Figure 1 - Timeline describing the sequence of events during the typesetting experiment

Initially, the participant starts gazing at the desired letter. When he completes a 500 ms time-interval of continuous gazing, the key is registered and simultaneously the associated visual indication is presented. The physiological responses following this indication are used to detect typesetting errors. We note that the "eye" icon was not presented in the experiments and it is only shown here for presentation clarity purposes

2.4 Primary, Secondary and Qualitative outcomes and statistical analysis

2.4.1 Primary Outcomes

The primary outcomes of the study were the impact of the MAMEM platform on the computer use habits and the social lives of the participants. In order to assess these two outcomes, we chose to extract usage measures that will represent each of these outcomes and will enable to assess the impact of the platform. For the computer use habits outcome, we extracted five measures of usage: i) active hours of usage, ii) unique sites that the user visited, iii) keystrokes that were made in the keyboard, iv) clicks that were made on the screen and v) typing speed (calculated as seconds per character). For impact on the social lives outcome, we chose the five most popular social sites and extracted three measures of usage in them: i) number of sessions, ii) total time spent in the site and iii) number of keystrokes that were made in the site. Finally, since the number of days with the system was different among the participants, we needed to create standardized measures that will allow comparisons without bias, so we divided each measure by the number of days that the participant had the system. To assess the primary outcome of the study, we chose to perform the analysis on the three users that used the system the most, from each clinical centre. This was done by calculating the average of active hours usage per day for each

participant and selecting the three participants that, on average, used the platform the most.

All of the above measures were calculated based on the usage data that was recorded for each participant using the built-in monitoring mechanism of GazeTheWeb.

2.4.2 Secondary Outcomes

The secondary outcomes consisted of user satisfaction and perceived usability of the system, as measured by the QUEST 2.0 and the SUS questionnaires, [8-9] respectively, in addition to the measurement of the evaluation of the persuasive design that was employed in the training games and in the design of the MAMEM dashboard and interface.

a) Satisfaction and perceived usability

The Satisfaction and perceived usability of the system were assessed using the SUS and the QUEST 2.0 questionnaires [9-10] that were used in Phase I of the trials (see [D6.4] [4]) and were administered in the final visit at the participants' home, after one month of using the system. The QUEST 2.0 items scores are averaged and the final score ranges between 1-5 (not satisfied at all – highly satisfied). The QUEST 2.0 scores were calculated by averaging the first part of the questionnaire that concerns the different physical and usability aspects of the assistive system. The SUS scores were calculated according to the standard way of calculation this questionnaire, [10] namely by assigning a relative score to each item and performing a calculation with their sum. The scores range between 0-100, and a SUS score above a 68 would be considered above average and anything below 68 is below average.

b) Evaluation of the persuasive design

The evaluation of the persuasive design was done using the persuasive design questionnaire that was used in Phase I of the trials (see D6.4 [4]). this questionnaire was passed after the participants did the training games and assessed their attitudes toward them and the platform.

The evaluation of persuasive design questionnaire was passed after the platform training part. The participants were explained that it is regarding the training games only. In Questions 1-4 the participants were asked to report whether the platform made them feel scared, nervous, unpleasant or uneasy by indicating whether they agree or disagree with corresponding statements on a scale of 1 (fully agree) to 7 (fully disagree). In question 1 the order of the answers was reversed to be compatible with the other questions. The following tables present the descriptive statistics regarding the first 4 questions. Question 5 asked the participants whether they believe they could operate the platform after they learned to use it alone, using the games or demonstrated how to use it by an instructor, by indicating whether they agree or disagree with corresponding statements on a scale of 1 (completely not sure) to 10 (completely sure). Questions 6-14 asked the participants to report on various

aspects of the platform such as its ease of use or pleasure, in addition to whether they believe they have enough knowledge to operate it or do they believe they had control over it by indicating whether they agree or disagree with corresponding statements on a scale of 1 (fully agree) to 7 (fully disagree). Questions 15-17 asked the participants to report on the personalization of the system and whether they believe the games that were used in the training stage motivated them. Finally, question 18 asked the participants whether they would use the system if it were available to them in the future. This was done by indicating whether they agree or disagree with corresponding statements on a scale of 1 (fully agree) to 7 (fully disagree).

2.4.3 Qualitative Outcomes

The qualitative outcomes in the current study were: patient testimonials, technical problems, experimenter impression of the participants, 2-week follow-up call data, case study analysis and, an experimenter diary.

a) Patients testimonials, technical problems, experimenter impression of the participants, experimenter diary and 2-week follow-up call data

To acquire these outcomes, we asked the experimenter in each clinical site to recap his/her experiences with the participants while performing the study and his/her interactions with the participants. In addition, for the participants' testimonials and for the 2-week follow-up call data, we performed qualitative structured interviews and questionnaires with the participants during their participation in the study and in the final visit.

b) Case study analysis

Case study analyses are called in to help build a series of hypotheses with regards to explaining the usage of MAMEM, the reaction to it and the adoption patterns exhibited by participants. Per cohort, two case studies were selected: a) the case of a participant who expressed high satisfaction with the use of MAMEM. The case analysis purports to generate hypotheses as to what contributes to a positive user experience in a participant with restricted mobility b) the case of a participant who expressed weaker desire to adopt the MAMEM technology. Again, here the analysis purports to provide possible explanations for understanding the reasons behind non-adoption of the MAMEM technology. An additional criterion which was used in determining participant eligibility for the case study analysis was the extent to which MAMEM was used. That is, more extensively and widely in the case of a successful case study and less widely so in the case of the negative case study.

User experience insights stemming from the case analyses will be further used in the MAMEM optimization steps. The main areas that the case study analyses touched were:

- Demographics: age and employment. The objective was to explore whether demographic elements may be purported to have an impact on the use and adoption of the device.
- Mobility status: The objective was to identify whether the extent of mobility restrictions may be an influential factor in reactions to MAMEM.
- History with digital devices: It was hypothesized that the degree of digital savvy, as well as the degree to which the participant is currently using digital devices at a highly comfortable level, or not, may impact reactions to MAMEM.
- Current digital device(s) used: explore whether the extent of use and level of comfort with existing devices may be an influential factor in reactions to MAMEM.
- Learning to use the device: We delved into what were challenges and strengths in learning to use the device. We need to build our understanding of what can be evolved in the MAMEM experience so as to facilitate learning to use it efficiently faster and easier.
- The experience of MAMEM over time: evaluate whether there was a learning curve that was important in the final reactions to MAMEM. We need to create hypotheses as to how long the familiarization process can be before the person acquires a comfort level, which allows expansive use.
- Range of MAMEM usage: explore whether there were areas of use to which participants tended to be more or less receptive to, given the MAMEM features.
- Critical satisfaction factors: understand which specific elements in the user experience may have contributed most to satisfaction with the device. Dissatisfactions with MAMEM: case study analysis can help us better understand what does not work, in which cases, under what conditions and why.
- Core learnings: we needed to build our understanding of MAMEM usage and develop possible explanations as to reactions to the user experience that will inform future research hypotheses and future research efforts.
- Future perspectives: identify possible steps that can be taken in the evolution and optimization of MAMEM technology and total proposition.

c) Multi-modal interface experience

The multi-modal interface experience was evaluated based on the experimenter on-site by observing the behaviour of the participants and the system. It's important to note that due to limitations that are described on Section 2.5, there was a selection of which participants should experience the multi-modal interfaces according to estimates on their motivation by each cohort personnel. This should be considered while analysing the qualitative outcomes of the study. Moreover, it should be taken into account that both of the experiments require significant BCI experience before they can work effectively, so the main focus of this study would not be to evaluate whether the system was working perfectly rather than focus on

the participant's experience. We have already realised from the beginning that having a (useful) BCI system that can work with a completely inexperienced BCI user on the first try was a totally unrealistic goal and thus we aimed to use this study to investigate whether a participant would be motivated enough to commit time and effort into learning how to use the system.

The qualitative outcomes that are examined are the following:

- Initial impression of the experimenter: The first impression of the experimenter when meeting the participant.
- Experience with the assistive devices: This is to evaluate whether the participant was willing to use the additional assistive devices (EEG, BIO-sensors).
- User motivation over time: This is to describe how motivated were the participant over the course of the experiment.
- Experience with the software: How quickly the user understood the instructions that were provided and learned how to use the system.
- Technical problems: Any technical problems that were encountered
- Performance of the system: The performance of the BCI system, i.e. whether the BCI commands were interpreted by the system according to the user's intentions.

The last four points will be examined separately for each of the two BCI interfaces (MM-Tetris & ErrP). The results are presented on Sections 3.1.5 and 3.2.5.

2.4.4 Statistical Analysis

Due to the low number of participants in each clinical group, we chose to not to perform statistical tests but instead to present descriptive statistics for the primary and secondary outcomes and to perform a complementary extensive qualitative assessment of the MAMEM platform usage as perceived form the participants' point of view.

2.5 Discussion/considerations/compromises

There were a few compromises during the Phase II trials, mainly due to the ecological nature of this type of trials, which meant that it was imperative to deal with the 'noisy' daily lives of the participants in a much less controlled environment. For instance, the attempt to keep a controlled schedule was often compromised by state holidays, sick leaves of the study personnel and also with events that took place in the participants' lives, such as hospital visits, sicknesses, travels and so forth. In addition, the study protocol meant leaving a computer and an eye-tracker at the participant's home, under their responsibility, while not being cared for by the experimenter, meaning that in this period of time, the apparatuses were possibly moved or used for other reasons other than study related. Consequently, during the study, two eye-trackers broke and became unusable. As previously mentioned, this was the reason that one participant was not included in the study.

Some additional compromises were due to the fact that some participants lived relatively far away from the clinical centres, which made the trips to their homes and back time effort consuming. These conditions led to some deviations from the study protocol such as not carrying out a pre-screening meeting, deviations in schedule due to efforts in coordination meeting, etc.

Another compromise rose from the long first visit of the study, which included passing out demographic, clinical and social questionnaires, installing the system, explaining how to operate it, performing the training games and more. Because of this and due to the disability of the study cohorts, it was decided beforehand that this long visit will be divided into two parts, including passing out some of the questionnaires over the phone in order to shorten the first visit. Despite that being done, during the study, it turned out that the first visit was still too long (in some cases 2.5 hours). For the SCI cohort, this visit was experienced as exhausting and therefore in all cases, it was decided to omit the training games and to focus on a short and effective "operating coarse". These participants were asked to perform the training games in the following days.

The compromises regarding the multimodal interfaces were the following:

- The multi-modal interfaces were tested only with a restricted number of selected patients that showed the highest enthusiasm about the platform and would be willing to go through the process of installing all necessary sensors for operating the multi-modal interfaces.
- It has been impossible to leave the EEG and GSR scanners to the participants for the whole duration of the Phase II trials for two reasons. Firstly, the EEG placement is a procedure that the majority of the caretakers recognized as difficult to complete without having the assistance of trained personnel. Secondly, a device as delicate as an EEG and GSR scanner could not be left to the sole responsibility of the participant and his/hers caretakers. Therefore, the EEG and GSR devices were only used during the experimenter's first day visit to the participants' home that were installed, under the experimenter's attention, together with the eye-tracker so as for the participants to experience the multi-modal interfaces. Upon his departure from the participant's home, the experimenter collected the EEG and GSR devices so as to be used for the next subject.
- The alternate scenario for gathering EEG measurements was for the experimenters to arrange home visits. This alternative was carried out only in one participant of the PD cohort (i.e. PD5)

2.6 Insurance

To provide insurance for the participants in phase II, AUTH and MDA Hellas purchased an insurance coverage plan from a commercial company that provides insurance for clinical trials. In Sheba, there was is an existing insurance plan that provides coverage for all the

experiments that take place in the hospital and so no extra insurance was needed to be purchased.

3 RESULTS

In the following sections we present the results of the trials of the three cohorts. There are three sub-sections, one for each cohort – participants with NMD, PD, and SCI. In each of these parts, we first describe the demographic, clinical and computer use data of the participants. Next, we present the primary outcomes for the three participants who used the system the most. We chose to do this due to the low number of participants for each group and due to the low usage rate for some of the participants in the study who chose to hardly use it. These conditions could create a false representation of the possible effect of the system on those who choose to use it and therefore that can benefit from it. Next, the secondary outcome for each cohort are presented and finally, a qualitative analysis of the participants' experience within the study is given.

In order to draw a wider conclusion about the platform, in the following section we perform a cross-cohort analysis of the system and attempt to discuss the results in a more wider point of view.

3.1 NMD Participants' Results

3.1.1 Demographical, Clinical and Computer Usage Data

In the next tables we report the demographic and clinical data of the NMD participants.

a) Demographical Data

	N	% / Average (SD)
Age	10	31.5 (4.8)
Education Years	10	15.5 (3.6)
Gender		
Male	6	60%
Female	4	40%
Marital Status		
Married	2	20%
Single	8	80%
Children No.		
0	10	100%
1	0	0%
2	0	0%
3	0	0%
Working		
Full-time	6	60%
Part-time	0	0%
No	4	40%
Hand preference		
Right	10	100.0
Left	0	0%

Table 1: Demographic characteristics of the NMD participants (n=10)

Looking at the demographic data of the NMD participants, it is possible to see that most of them are not married, more than half of them are working fulltime and that none of them have any children.

b) Clinical Data

	N	% / Average (SD)
Diagnosis		
Muscular dystrophy	3	30%
Arthrogryposis multiplex congenita	1	10%
Duchenne muscular dystrophy	3	30%
Stiff Person syndrome	1	10%
SMA II	2	20%
Years with a NMD	10	15.7 (12.6)
Spinal surgery		
Yes	2	20%
No	8	80%
Use wheelchair		
yes	10	100%

Table 2: Clinical characteristics of the NMD participants (n=10)

	Tongue		Jaw		Neck		Shoulders		Arms		Elbows		Wrists		Hands		Fingers	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
No Symptom	6	60%	5	50%	3	30%	1	10%	1	10%	1	10%	2	20%	2	20%	1	10%
Partial	4	40%	4	40%	7	70%	7	70%	4	40%	5	50%	4	40%	3	30%	7	70%
Complete	0	0%	1	10%	1	10%	2	20%	5	50%	4	40%	4	40%	5	50%	2	20%

Table 3: Distribution of partial or complete bradykinesia/numbness/immobility among the NMD participants (n=10)

The clinical data of the NMD participants indicates that all of them use wheelchairs and most of them suffer from bradykinesia/numbness/immobility in body parts that are necessary for computer operation.

c) Computer Usage Data

The following table present the participants' perceived impact of the disability on their social lives according to the question: "How is your social life affected by your disability?".

	frequency	percent
My social life is normal	4	40%
There is no significant effect on my social life apart from limiting energetic aspects, such as dancing	5	50%
My social life is restricted, and I do not go out as often	1	10%
My social life is restricted to my home	0	0%
I have no social life and feel lonely	0	0%

Table 4: NMD participants' perceived impact of their disability on their social lives (n=10)

Most of the NMD participants report that their disability has no significant effect of their social lives. The following table present the NMD participants' perceived impact of the disability on outdoor mobility.

	frequency	percent
I travel frequently for needs / pleasure	4	40%
I travel sometimes	6	60%
I travel very rarely and only when there is an absolute need	0	0%
I cannot travel and must stay home	0	0%

Table 5: Impact of the disability on NMD participants' mobility outdoors (N=10)

Most of the NMD participants report normal mobility of a small limitation in their mobility. The following table presents the computer use habits of the participants.

	N	% / Average (SD)
Digital devices owned		
Desktop computer	9	90%
Laptop computer	8	80%
Tablet	4	40%
Smartphone	9	90%
Use a computer		
Yes	10	100%
Average hours of computer use per day	10	6.7 (2.7)
Years of experience of operating computers	10	14.3(8.8)
Operating system		
Windows	9	90%
Apple OS	1	10%

Table 6: Computer use habits of the NMD participants (N=10)

The NMD participants own many digital devices including computers and smartphones. They use computers for significant durations and report having many years of experience using it.

The participants were asked to report which digital device they used the most. The following figure presents their answers.

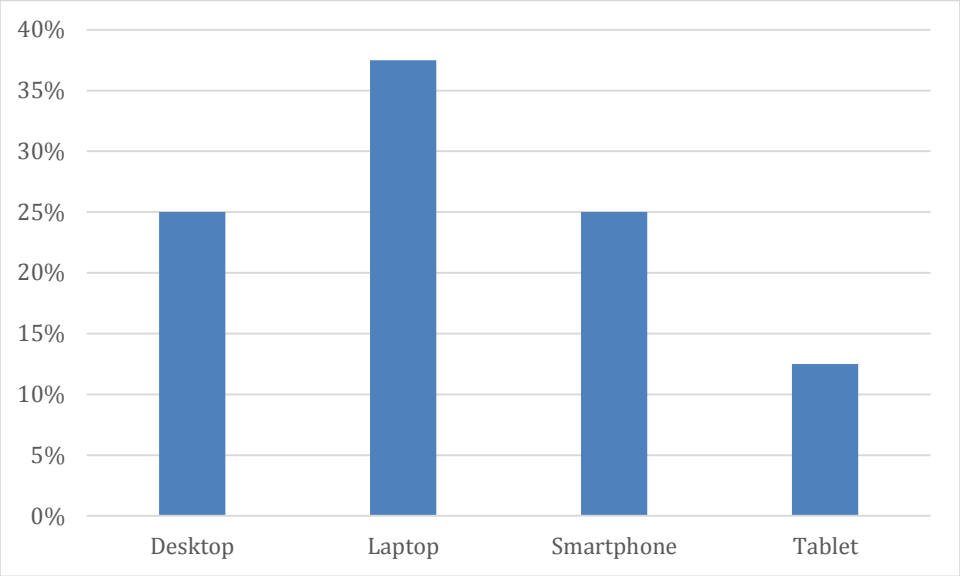

Figure 2 - Digital device use patterns by the NMD participants (n=10)

Most of the NMD participants report using their laptop the most. The following table presents the answers for the question: "To what extent do your physical symptoms impair your ability to use the computer as extensively and as widely as you might like?".

	frequency	percent
My symptoms do not interfere at all with my ability to use the computer	2	20%
My symptoms interfere a slightly	5	50%
My symptoms interfere fairly much	2	20%
My symptoms interfere very much	1	10%
I am not sure/I do not know	0	0%

Table 7: the NMD participants physical symptoms' perceived effect of on computer operation (n=10)

Most of the NMD participants report a slight interference of their clinical condition on their computer use. The following tables present the main computer uses of the participants and the main applications that the participants reported using.

	frequency	percent
Social participation (Facebook, forums, etc.)	8	80%
Productive activities (writing, editing, etc.)	3	30%
Study (on-line courses, articles, etc.)	5	50%
Games	1	10%
Recreation (movies, music, crossword puzzles, blogs, etc.)	3	30%
Communication (email, Skype, etc.)	7	70%
Activities of daily living (purchases, payments, bank, etc.)	2	20%
Information (Wikipedia, governmental sites, news, maps, etc.)	0	0%
Other	0	0%

Table 8: Main computer uses of the NMD participants (n=10)

It seems that the most important computer uses of NMD participants are social participation, and communication.

	frequency	percent
Internet browser	9	90%
Email client	6	60%
Word processor	6	60%
Audio/video/image applications	2	20%
Spreadsheets (e.g. Excel)	0	0%
Computer games	1	10%
Presentation software	0	0%
Programming/database	1	10%
Media editing applications	3	30%
Other	1	10%

Table 9: Main computer uses of the NMD participants (n=10)

It can be seen that interned browsing is the most important computer use for the NMD participants and thus, GazeTheWeb could serve as an essential tool for them for this purpose.

3.1.2 Primary Outcomes

The following figure presents the average active usage hours per day for NMD participants.

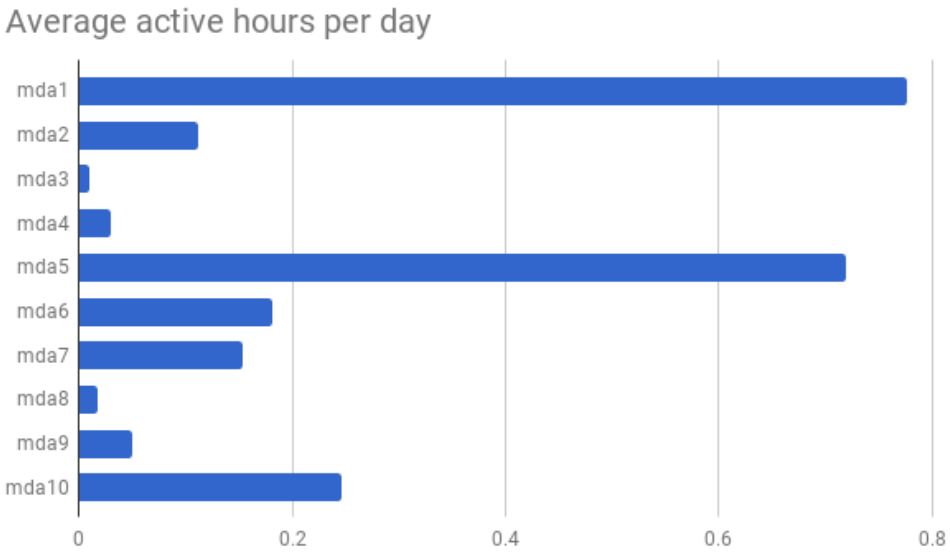

Figure 3 – NMD participants average active usage hours per day

Looking at Figure 2, we may categorize NMD participants in three categories, i.e. ones that used the system very little (mda3, mda4, mda8 and mda9), users that made moderate use (mda2, mda6, mda7) and users that made frequent use (mda1, mda5 and mda10). Based on this categorization, the participants: 'mda1', 'mda5' and 'mda 10' were selected from the MDA Helllas centre to be investigated further. The next three Sections address the performance of these participants.

a) General Usage Outcomes

The usage primary outcomes were calculated for each of the chosen participants. These outcomes appear in the following tables.

Participant	Active hours per day	Unique sites per day	Keystrokes per day	Click per day	Typing speed per day (seconds per character)
Mda1	0.77	3.93	40.8	70.1	3.87
Mda5	0.71	1.9	123.72	39.96	1.59
Mda10	0.24	2.03	25.92	14.32	0.89

Table 10: NMD participants general usage primary outcomes (n=3)

It is noticeable that the two participants that used the platform the most differ in their usage patterns considerably so that mda1 visited twice as much sites, performed half as much keystrokes, but twice as much clicks, and types considerably slower than mda5.

b) Activity in Social Media Sites Outcomes

To calculate the social activity primary outcomes, the activities in social media sites per day were calculated in the same manner as above for five of the most popular social media sites. These outcomes appear in the following table.

Participant	Facebook			Instagram		
	sessions	Time spent	Keystrokes	sessions	Time spent	Keystrokes
Mda1	4.13	0.28	22.76	1.13	0.03	1.2
Mda5	1.9	0.05	84.56	0.23	-	1.46
Mda10	0.2	-	2.86		-	-
	Twitter			YouTube		
	sessions	Time spent	Keystrokes	sessions	Time spent	Keystrokes
Mda1	0.53	-	0.63	1.56	0.08	4.8
Mda5	0.8	-	-	1.53	0.28	30.53
Mda10	-	-	-	0.4	0.04	1.96
	Email					
	sessions	Time spent	Keystrokes			
Mda1	2.1	0.03	1.76			
Mda5	-	-	-			
Mda10	0.16	-	-			

Table 11: NMD participants' activity in social media sites primary outcomes (n=3)

It seems that mda5 spent considerable time using the keyboard in Facebook and YouTube, which fits his usage patterns.

c) Most Popular Websites Outcomes

The outcomes regarding the most visited websites appear In the following tables.

Participant	1st most popular website	sessions	Time spent (hours)	Keystrokes
Mda1	Novasports.gr	18	1.35	-
Mda5	Newsit.gr	61	0.57	11
Mda10	Google.gr	29	0.52	-

Table 12: NMD participants primary outcomes in most popular websites (n=3)

The most popular sites among the chosen NMD participants are sport, news and search sites.

3.1.3 Secondary Outcomes

a) Satisfaction and Perceived Usability

The following table presents descriptive statistics of the SUS and QUEST 2.0 scores that were given to the platform by the NMD.

	Average	SD
SUS	70	17
QUEST 2.0	3.8	0.62

Table 13: NMD participants descriptive statistics for the SUS and QUEST 2.0 SCORES (n=10)

The average SUS score given to the MAMEM platform by the NMD participants is considered 'above average'. The average QUEST 2.0 score given to the MAMEM platform by the NMD participants is considered average.

b) Evaluation of Persuasive Design

	Average	SD
The MAMEM system did not scare me at all	1.8	1.87
Operating the MAMEM system made me nervous	5.1	2.46
The MAMEM system made me feel uncomfortable	5.5	2.12
The MAMEM system made me feel uneasy	4.8	2.2

Table 14: NMD participants descriptive statistics from the evaluation of persuasive design questionnaire – questions 1-4 (n=10)

Results of questions 1-4 in the persuasive design questionnaire suggest that the NMD participants felt quite comfortable with the MAMEM platform.

		Average	SD
I could complete the training tasks using the MAMEM system…	…if there was no one around to tell me what to do.	4.1	2.46
	…if I had just the build-in practice games for practicing	5.5	2.41
	…if someone showed me how to do it first.	8.1	1.26

Table 15: NMD participants descriptive statistics from the evaluation of persuasive design questionnaire – question 5 (n=10)

Results of question 5 suggest that the NMD participants think that training games gave a small advantage over learning how to use the system on their own.

	Average	SD
I had control over using the MAMEM system	5.5	1.26
I have the skills and knowledge necessary to use the MAMEM system	6.2	1.13
Given the skills and knowledge it takes to use the MAMEM system, it was easy for me to use the MAMEM system	5.7	1.76
My interaction with the MAMEM system was clear and understandable	6.3	1.05
I find the MAMEM system to be easy to use	5.6	1.89
I find it was easy to get the MAMEM system to do what I want it to do	6.4	0.69
I find using the MAMEM system enjoyable	5.8	1.61
The actual process of using the MAMEM system was pleasant	4.8	1.98
I had fun using the MAMEM system	5.9	1.19
I had control over using the MAMEM system	5.5	1.26

Table 16: NMD participants descriptive statistics from the evaluation of persuasive design questionnaire – questions 6-14 (n=10)

Results of questions 6-14 in the persuasive design questionnaire show that the NMD participants tend to find the MAMEM easy to use and enjoyable.

	Average	SD
The training tasks motivated me to train my MAMEM skills (e.g., focus with my eyes, scroll the screen down, etc.)	6.4	0.84
The games in the training tasks (e.g., collecting points) motivated me to do those tasks	6.2	0.78
I had the feeling that the messages of the MAMEM system were intended for me	4.6	2.06
Assuming I had access to a MAMEM system, I intend to use it	5.5	1.50

Table 17: NMD participants descriptive statistics for the evaluation of persuasive design questionnaire – questions 15-18 (n=10)

Results of questions 15-18 in the persuasive design questionnaire show that the NMD participants report high motivation of using the system, average levels of personalization, and an average level of intention for using it in the future.

3.1.4 Qualitative Outcomes

a) Participants' Testimonials

The participants were asked to provide their impressions on their experiences with operating the platform during the one month. Their inputs were recapped by the study personnel and summarized or quoted below.

MDA1	"the platform had no flash support. It sometimes needed to be re-calibrated, and most of the time in the beginning, I needed to pull out and put the USB again".
MDA2	"It is really nice and useful, and I enjoyed it. Eye tracker problem during the last week. If a user cannot move his/her hands how could a stand-by mode be deactivated? How he will plug the eye tracker in and out? I believe it can be very useful to many people".
MDA3	He had difficulty in writing using his eyes but believes that if you are familiar with the platform, it can be useful to many people.
MDA4	-
MDA5	She used the computer for 2 to 5 hours per day, while her previous use was almost zero, reopened her Facebook accounts and Instagram, managed to communicate with a person abroad, entertained by YouTube. In addition, she said usage was

	getting easier and faster as time went by. Finally, on organizing a trip that took place through the use of MAMEM system, it was reported that the system helped her to organize better and improved her life. She did not report particular problems, other than she sometimes needed to restart the system.
MDA6	He reported: Easy learning of the program. From the first time he used, he knew how to operate it. When he had to stop using it for a while for some reason and came back he needed calibration again. His eyes got tired quickly, so he could not use it for hours. With his current clinical characteristics, he would not replace his computer with MAMEM, mainly because of fatigue. Several times the program crashed, and he needed to restart the system.
MDA7	He reported: If you are familiar with the system, it is easier for you. It affects the human-computer interaction because it helps a lot. It positively affects job opportunities because it offers regular computer usage that he did not have before.
MDA8	-
MDA9	He reported: The system works well and is easily manageable. Many times, he needed to restart it. On the 1st day it was quite difficult to use. He mentioned two reasons that might have been. Initially, a fluorescent lamp was lit behind it and might have affected the sensors. He also did not connect the power cable and when did, it worked normally. When he had to stop using it for a while due to some reason and came back he needed calibration again. Would like to have a button to place the cursor in the text instead of having to use the arrow keys to move the cursor to correct something. On Facebook, he could not comment on the home page.
MDA10	Several times the program crashed, and he needed to restart the system.

b) Technical problems

The participants were also asked to report any technical difficulties they encountered while using the platform. The following table presents the technical problems that were reported for each participant.

MDA1	The participant did not have enough space for the system, so he asked to use the system instead of his personal computer. For this reason, we also had to install additional software that was important for the participant. We noticed that the participant had problems to accurately use the eye-tracker during the training stage, but he managed to solve this problem on his own later. The participant also

	mentioned that the eye-tracker crashed frequently, meaning that he had to re-plug the eye-tracker on the USB port to fix it.
MDA2	The participant asked to set the system up on small table in the kitchen, which might not be the ideal environment for using the system. The participant also mentioned that the eye-tracker crashed frequently, meaning that she had to re-plug the eye-tracker on the USB port to fix it.
MDA3	The participant mentioned that he had trouble selecting things with the eye-tracker (Midas problem).
MDA4	The participant mentioned that the system failed to playback videos on the Facebook website. He also wanted to watch a movie using the system but was unable to do so.
MDA5	The participant mentioned that the eye-tracker crashed frequently, meaning that he had to re-plug the eye-tracker on the USB port to fix it.
MDA6	No problems were reported.
MDA7	The participant mentioned that he was unable to watch livestream videos.
MDA8	No problems were reported.
MDA9	The participant mentioned that the eye-tracker crashed frequently, meaning that he had to re-plug the eye-tracker on the USB port to fix it.
MDA10	No problems were reported.

c) Experimenters' Impression from the Participants

In this part, we bring the qualitative impression of the experimenter from the participants.

MDA1	He was excited in his participation. He was the only one who replaced his own laptop during the trial. During the training, he was faced with some focusing issues, but when he was familiar with the system, he did not have much trouble.
MDA2	In general, the participant was positive on the experience. However, he did complain about the eye tracker problem during the last week. The participant believes the platform to be very useful.
MDA3	His clinical characteristics and the good functionality in his hands made him not so interested.

MDA4	The system was not functional for her due to completely different work demands she has from the computer. It was difficult for her to use it only for social media, as she had to work on another computer anyway. Before dropping out, she also said that her use did not affect communication with people in social media at all, since she could do it before.
MDA5	She was the only participant who, when returning the equipment, told us that she would miss it. Further, she called us after a few weeks to ask if she would again have the opportunity to use it through the program or if she could buy it from somewhere.
MDA6	He was positive on the experience.
MDA7	He was positive on the experience.
MDA8	The participant could not focus and control gaze direction of his one eye causing unsuccessful operation of the system.
MDA9	He was positive on the experience.
MDA10	He was positive on the experience.

d) 2-week Follow-up

	Average	SD
On a scale of 10 to 1, how satisfied are you using MAMEM, up to this point? Where 10 means 'very satisfied' and 1 means 'not at all satisfied'	6.5	2.80
In comparison to the previous digital device, how satisfied are you with MAMEM, on a scale of 1 to 5, where 5 is 'by comparison more satisfied' and 1 is 'by comparison not at all satisfied'	3	1.70
Now that you have tried MAMEM for 2 weeks, how probable is it that you would recommend it to a person in your condition on a scale of 10 'would definitely recommend' to 1 'would not at all recommend'?	7.6	2.84

Table 18: NMD Participants' answers to the 2-week phone call questionnaire (n=10)

In the two-week call, the NMD participants report high satisfaction of using the MAMEM platform, that they are satisfied with it in the same level as their previous digital device and that they would definitely recommend it to other people in their condition.

e) Case-Study Analysis

A case study analysis of an NMD participant reporting high satisfaction with MAMEM

Demographics	37-year-old female, NMD sufferer, employed as a special education teacher in a special education school. She lives with her parents who are the core caretakers, and with her sister who is also an NMD patient.
Mobility status	She suffers from complete immobility from the neck down and is fully dependent on a wheel chair. She has no mobility in the hands. She goes to work daily, and her father takes care of all of her transfer needs. She is fully dependent on others in order to move around.
History with digital device use	Some years back she had been using a laptop computer and social media, but it has been at least 4 years now that her symptoms have progressed, and she is not able to use it at all, any more. She has disabled her Facebook, Twitter and Instagram accounts since around 4 years ago.
Current digital device used	She is only able to use an e-reader, and reading books is a daily activity for her, the only digital activity she engages in. She has timed her e-reader so as to turn pages at set times, enabling her to read books as her main hobby and pastime at home.
Learning to use the device	This participant mentioned that she was able to learn to use the device fairly fast and easily, in her own opinion. Other participants, with better hand mobility, mentioned that eye focusing took some learning and could be rather tiring. In their case, MAMEM took some time getting used to and its use in the first days was challenging. However, this participant seems to have been so eager to acquire access to a computer, that nothing about MAMEM felt to be challenging or difficult. She did mention that using MAMEM became easier over time, but she never expressed any challenge during the first days.
The experience of MAMEM over time	This participant went from using the computer zero times a day, to using the computer 2 – 3 hours every day. She mentioned that this had tremendous impact in her life as it opened up a wide range of opportunities to learn, to connect and to be entertained.
Range of MAMEM usage	This participant started using Facebook and Instagram again. She started using YouTube for entertainment, and she mentioned browsing the internet avidly in order to get information on subjects she is interested in, both job and health related aspects.
Critical satisfaction factors	This participant mentioned a radical difference in her life due

	to MAMEM, in a sense that it actually gave her access to the internet, where beforehand, none was possible. When she had to give up the device at the end of the month, she stated that she would deeply miss all the activities that she was able to carry out with it. The critical satisfaction factor in terms of using MAMEM was, for her, the gift of independent use of the internet. In the past, whenever she wanted to use the internet she had to engage a care taker and give them instructions about what to do and which sites to visit. This deprived the participant of both independence and privacy, while making her feel that the usage of internet was a burden to her caregivers.
Dissatisfactions with MAMEM	The only dissatisfaction mentioned was that the system required frequent restarts due to frequent crashes.
Core learnings from this case	The most important insight to be gleaned from this case of successful adoption of MAMEM is that people with major hand mobility problems are likely to experience a big positive impact out of MAMEM'S use, especially if they are not currently using any assistive device that allows internet use. It is reported that the fact that MAMEM allows independent, efficient, and fairly fast use of the computer and of the internet, has a big impact on a person's day to day living.
Future perspectives	NMD is a progressive disease. It is rarely the case that NMD symptoms do not progress. It will be important to educate both NMD patients as well as their care takers that when MAMEM is adopted early enough, when the hands are still even minimally agile, then there should not be a period when the disabled persons' access to a computer is totally discontinued.

A case study analysis of an NMD participant reporting lower satisfaction with MAMEM

Demographics	26-year-old male, a student of photography. He lives with his parents and a much younger sister.
Mobility status	The participant suffers from NMD. He is wheelchair bound, but has full use of his hands, currently, from the elbow down. He is able to bring a glass to his mouth and is able to handle his wheelchair on his own. He is independent when it comes to moving around. He is able to use public transportation on his

	own, and he never hesitates to ask for the help of strangers in the street when encountering obstacles or challenges as he moves around.
History with digital device use	He is fully digitally efficient. He is a "digital native" in that he grew up using digital devices, especially his mobile phone. It is very important to note that these individuals, who have grown up closely linking their daily life and experiences with the use of technology, will be the ones who may be affected the most if their symptoms progress and their hand mobility decrease. These are the kinds of individuals that MAMEM is meant for the most. With progressive disease symptoms, like those of NMD, this participant in the future, should he lose his hand mobility, will not be doomed to exclusion from a digital life.
Current digital device used	He is a very heavy user of his mobile phone, using it to connect to social media, listen to music and be entertained on YouTube, while on the go. When at home, he prefers to use a laptop, and he does so spending several hours online, while at home.
Learning to use the device	This participant has mentioned that he became very impatient during learning to use the device. That is, learning how to focus accurately and for the right amount of time, each time. He is already extremely fast and efficient in using his laptop and mobile phone, so the learning process had him slowing down, to use his eyes to handle the device. However, he did mention that as time progressed, he was able to become faster using MAMEM.
The experience of MAMEM over time	This participant mentioned that he does not experience any major difference in the quality of his digital activities. When away from home, his mobile phone remains the only way he can have digital connections. When at home, he states that he finds it easier and smoother to keep using his conventional laptop. Here, it can be seen clearly that in cases when there is still some mobility in the hands, the conventional technology habit is prevalent and is not easily dislodged or replaced. What is not clear is the following question that is beyond the scope of this study: if this young participant were to use MAMEM over a longer stretch of time, would he become as fast with it, as with conventional technologies? And in that case would it be relieving for him to be using his eyes for the device, so as to make it possible to overwork his hands less,

	given the fact that his hands have to also deal with the wheelchair handling? In addition, would using the computer with his eyes allow him to use his hands elsewhere, so that this kind of multitasking might become his competitive advantage?
Range of MAMEM usage	This participant used MAMEM at exactly the same activities, as was the case with his conventional devices. However, MAMEM did not replace the use of his mobile phone.
Critical satisfaction factors	This participant did not experience an element of superiority of MAMEM over using his conventional devices.
Dissatisfactions with MAMEM	The core dissatisfaction was that using MAMEM slowed him down, versus his other laptop device at home. As a result, he expressed a weak intention with regards to using the MAMEM device.
Core learnings from this case	The insight to be gleaned from this case study of a less enthusiastic MAMEM user is that: when hand mobility is high, then there can be some resistance to adopting MAMEM, due of the strength of the habit. Such resistance is related to the efficiency and comfort of using conventional devices. However, it is important for victims of a progressive diseases like NMD to be aware of available tools for them to use, should they ever experience hand mobility problems. We esteem that this knowledge will be empowering in their ultimate attitude towards their life and their future.
Future perspectives	It would be interesting to explore in future studies if MAMEM could take multitasking to the next level, creating a competitive advantage to otherwise less mobile individuals. For example, browsing the internet while also doing hand workouts.

3.1.5 Multi-modal interfaces

Results for **MDA1** participant:

Initial impression of the experimenter	It is evident that the participant is spending a lot of time during the day in front of a computer. His condition still allows him to use his own computer with a mouse but without being comfortable on doing so. He was very positive on participating on this experiment. From our understanding, he was very experienced with technology, since he was using a lot of sophisticated software on

	his computer, e.g. for changing TV channels.
Experience with the assistive devices	There were some minor problems about the EEG device which was not fitting very well with his wheelchair, but they got resolved quickly after some adjustments. He also was using a breathing device when we arrived which we asked him to remove before the BCI experiments. He would not be able to use both of the devices at the same time but he had no problem with that.
MM-Tetris	
User motivation over time:	The participant was highly motivated during the whole course of the experiment. In the end, even if he seemed tired, he wanted to perform an additional Tetris session in order to improve his score. Overall, it seemed like a good experience for him.
Experience with the software	The participant understood the instructions very quickly. No issues with the software.
Technical problems	No technical problems.
Performance of the system	The participant seemed to control the EEG part of the MM-Tetris really good, the tetriminoes usually stopped rotating in favorable positions. However, due to some misplacement of two tetriminoes he only managed to score 2 lines. On the second session he played a little better, scoring 5 lines.
ErrP gaze keyboard	
User motivation over time:	The user was a bit tired when starting the ErrP experiments and he asked to stop after we explained the protocol to him.
Experience with the software	The experiment was not performed.
Technical problems	No technical problems.
Performance of the system	The experiment was not performed.

Results for the **MDA2** participant:

Initial impression of the experimenter	The participant is in a relatively good condition allowing her to move without a wheelchair around the house and use a typical laptop for her online activities. She was very positive about the study and helped on finding space for placing the system. She was in a very good mood and made jokes all the time.
Experience with the assistive devices	It was her first time using an EEG device and didn't know much about it. For this reason, she was scared of using it at first, but after some clarifications she felt better. Overall, she was neutral about the device i.e. no big complains about it but not excited to

	use it either.
MM-Tetris	
User motivation over time:	The participant was highly motivated during the whole course of the experiment. When the BCI did not work properly she always thought that she had done something wrong, but we reassured her that this was a challenging task for a first time BCI user.
Experience with the software	The participant seemed to understand the instructions on how to play the game quickly.
Technical problems	No technical problems.
Performance of the system	The participant tried really hard, but could not control the rotation of the tetriminoes very well. However, she managed to score 4 lines by placing the tetriminoes smartly on the board.
ErrP gaze keyboard	
User motivation over time:	The participant was feeling a bit stressed because she was making too many mistakes. We explained her that the point of this experiment was to make typing mistakes and to not worry. She was really trying hard to perform well.
Experience with the software	The participant was making a few more mistakes than expected while typing. However, it seemed that after a while she was getting used to the keyboard and typed more efficiently.
Technical problems	No technical problems.
Performance of the system	We asked the participant to type a few sentences for testing the system. We believe that due to the somewhat high number of mistakes during the calibration step, the classifier was a little bit biased on deleting more letters than necessary. The system was deleting most of her mistakes, but there were some instances that a correct letter was deleted.

Results for the **MDA3** participant:

Initial impression of the experimenter	This is a young participant in a relatively good condition. He can use his hands effectively to use a typical laptop for his hobby activities (photography, gaming). He was very talkative and willing to help.
Experience with the assistive devices	It was his first time using an EEG device, but he it was explained to him beforehand what it is about. He didn't have any problems with wearing a device. He seemed like a person who embraces technology and willing to try new things.
MM-Tetris	
User motivation over	The participant started by being very cooperative, he seemed very

time:	interested on what we do. While playing MM-Tetris, he had some unrealistic expectations about the game, and was a bit disappointed that he could not control it 100%. We explained to him that he was doing very well, and that it was a challenging task. Nevertheless, he liked the experience of the game so he asked to play more than what it was necessary for the experiment.
Experience with the software	No issues with the software, he understood all the instructions quickly.
Technical problems	The router kept restarting 2 or 3 times during the experiments which caused some minor interruptions.
Performance of the system	The participant had a nice start but after some mistakes he restarted the game twice. He played one complete session during which he managed to score 3 lines.
ErrP gaze keyboard	
User motivation over time:	The participant was a bit tired after the MM-Tetris session but agreed to continue the study. He completed all the sentences of the protocol but we felt that he wasn't trying too hard in the process and he just wanted to finish the study.
Experience with the software	The participant had trouble understanding the instructions of the experiment such as that he was not supposed to correct the letters and keep going after a typing mistake. He also had some minor problems with the dwelling time but he got used to it quickly. He was typing some sentences wrong during the training process but for most of them we didn't bother him to repeat them because he was already feeling tired and we did not want to pressure him too much.
Technical problems	No technical problems.
Performance of the system	After the calibration stage, he was asked to type a few sentences to try the correction mechanism. The system was not working properly but was not completely a failure either. In some instances, the system identified and corrected some mistakes. We definitely felt that he had the potential to improve the classifier if he was given a chance for more training sessions.

3.2 PD Participants' Results

3.2.1 Demographical, Clinical and Computer Usage Data

In the next tables we report the demographic and clinical data of the PD participants.

a) Demographical Data

	N	% / Average (SD)
Age	10	55.6 (7.3)
Education Years	10	16.2 (3.8)
Gender		
Male	6	60%
Female	4	40%
Marital Status		
Married	10	100%
Single	0	0%
Children No.		
0	0	0%
1	3	30%
2	7	70%
3	0	0%
Working		
Full-time	6	60%
Part-time	0	0%
No	4	40%
Hand preference		
Right	10	100.0
Left	0	0%

Table 19: Demographic characteristics of the PD participants (n=10)

Looking at the demographic data of the PD participants, it is possible to see that all of them are married, they have more education than the other cohorts and more than half of them are working fulltime.

b) Clinical Data

	N	% / Average (SD)
Years with a Parkinson's disease	10	10 (4)
H&Y scale	10	2.1 (0.3)
Use wheelchair		
yes	0	0%
No	10	100%

Table 20: Clinical characteristics of the PD participants (n=10)

	Tongue		Jaw		Neck		Shoulders		Arms		Elbows		Wrists		Hands		Fingers	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
No Symptom	10	100%	10	100%	10	100%	8	80%	6	60%	1	10%	0	0%	0	0%	0	0%
Partial	0	0%	0	0%	0	0%	1	10%	3	30%	8	80%	9	90%	9	90%	9	90%
Complete	0	0%	0	0%	0	0%	1	10%	1	10%	1	10%	1	10%	1	10%	1	10%

Table 21: Distribution of partial or complete bradykinesia/numbness/immobility among the PD participants (n=10)

	Tongue		Jaw		Neck		Shoulders		Arms		Elbows		Wrists		Hands		Fingers	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
No Symptom	10	100%	10	100%	10	100%	10	100%	10	100%	5	50%	2	20%	2	20%	1	10%
Partial	0	0%	0	0%	0	0%	0	0%	0	0%	3	30%	6	60%	6	60%	7	70%
Complete	0	0%	0	0%	0	0%	0	0%	0	0%	2	20%	2	20%	2	20%	2	20%

Table 22: Distribution of tremor among the PD participants (n=10)

	Tongue		Jaw		Neck		Shoulders		Arms		Elbows		Wrists		Hands		Fingers	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
No Symptom	10	100%	9	90%	9	90%	9	90%	9	90%	9	90%	7	70%	6	60%	6	60%
Partial	0	0%	1	10%	1	10%	1	10%	1	10%	1	10%	3	30%	4	40%	4	40%
Complete	0	0%	0	10%	0	10%	0	10%	0	10%	0	10%	0	0%	0	0%	0	0%

Table 23: Distribution of dyskinesia among the PD participants (n=10)

The clinical data of the PD participants indicates that none of them use a wheelchair, while all of the participants in the other cohorts do. While they suffer from low levels of dyskinesia, they seem to suffer from high levels of tremors and bradykinesia in their arms, hands and fingers - body parts that are necessary for computer operation.

c) Computer Usage Data

The following table present the PD participants' perceived impact of the disability on their social lives according to the question: "How is your social life affected by your disability?".

	frequency	percent
My social life is normal	4	40%
There is no significant effect on my social life apart from limiting energetic aspects, such as dancing	3	30%
My social life is restricted, and I do not go out as often	2	20%
My social life is restricted to my home	1	10%
I have no social life and feel lonely	0	0%

Table 24: PD participants' perceived impact of their disability on their social lives (n=10)

Some of the PD participants report that their disability has no significant effect of their social lives. However, most of them report some restrictions. The following table present the PD participants' perceived impact of the disability on outdoor mobility.

	frequency	percent
I travel frequently for needs / pleasure	4	40%
I travel sometimes	3	30%
I travel very rarely and only when there is an absolute need	2	20%
I cannot travel and must stay home	1	10%

Table 25: Impact of the disability on PD participants' mobility outdoors (N=10)

Most of the PD participants report some restrictions of their mobility due to their condition. The following table presents the computer use habits of the participants.

	N	% / Average (SD)
Digital devices owned		
Desktop computer	7	70%
Laptop computer	7	70%
Tablet	4	40%
Smartphone	3	30%
Use a computer		
Yes	10	100%
Average hours of computer use per day	10	3.7 (2.2)
Years of experience of operating computers	10	21.9 (10.4)
Operating system		
Windows	9	90%
Apple OS	1	10%

Table 26: computer use habits of the PD participants (N=10)

Most of the PD participants own a computer, but only 3 have smartphones. They use computers for significant duration and have many years of experience using it. The participants were asked to report which digital device they used the most. The following figure presents their answers.

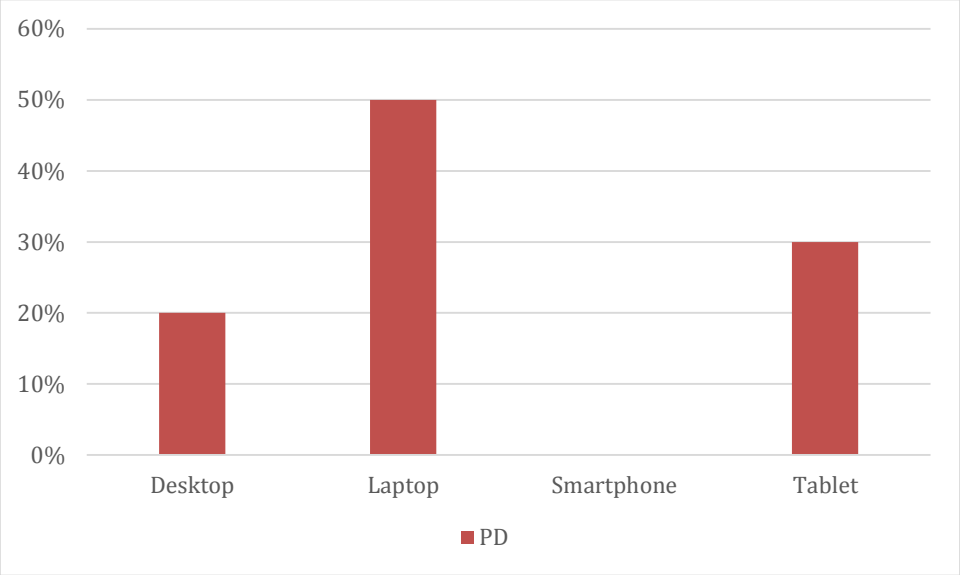

Figure 4 - Digital device use patterns by the PD participants (n=10)

Most of the PD participants report using their laptop the most, while none report using their smartphone the most. The following table presents the answers for the question: "To what extent do your physical symptoms impair your ability to use the computer as extensively and as widely as you might like?".

	frequency	percent
My symptoms do not interfere at all with my ability to use the computer	0	0%
My symptoms interfere a slightly	5	50%
My symptoms interfere fairly much	4	40%
My symptoms interfere very much	1	10%
I am not sure/I do not know	0	0%

Table 27: the PD participants physical symptoms' perceived effect of on computer operation (n=10)

None of the PD participants reported no interference, and most report of slight-medium interference of their clinical condition on their computer use. The following tables present the main computer uses of the participants and the main applications that the participants reported using.

	frequency	percent
Social participation (Facebook, forums, etc.)	1	10%
Productive activities (writing, editing, etc.)	4	40%
Study (on-line courses, articles, etc.)	5	50%
Games	2	20%
Recreation (movies, music, crossword puzzles, blogs, etc.)	3	30%
Communication (email, Skype, etc.)	5	50%
Activities of daily living (purchases, payments, bank, etc.)	4	40%
Information (Wikipedia, governmental sites, news, maps, etc.)	5	50%
Other	1	10%

Table 28: Main computer uses of the PD participants (n=10)

It seems that the most important computer uses of PD participants are study, information and communication, and only one participant reports using computers for social participation.

	frequency	percent
Internet browser	9	90%
Email client	9	90%
Word processor	7	70%
Audio/video/image applications	3	30%
Spreadsheets (e.g. Excel)	2	20%
Computer games	1	10%
Presentation software	0	0%
Programming/database	0	0%
Media editing applications	0	0%
Other	2	20%

Table 29: Main computer uses of the PD participants (n=10)

It can be seen, that in this case as well, interned browsing is one of the two most important computer uses and thus, GazeTheWeb could serve as an essential tool for them for this purpose.

3.2.2 Primary Outcomes

The following figure presents the average active usage hours per day for PD participants.

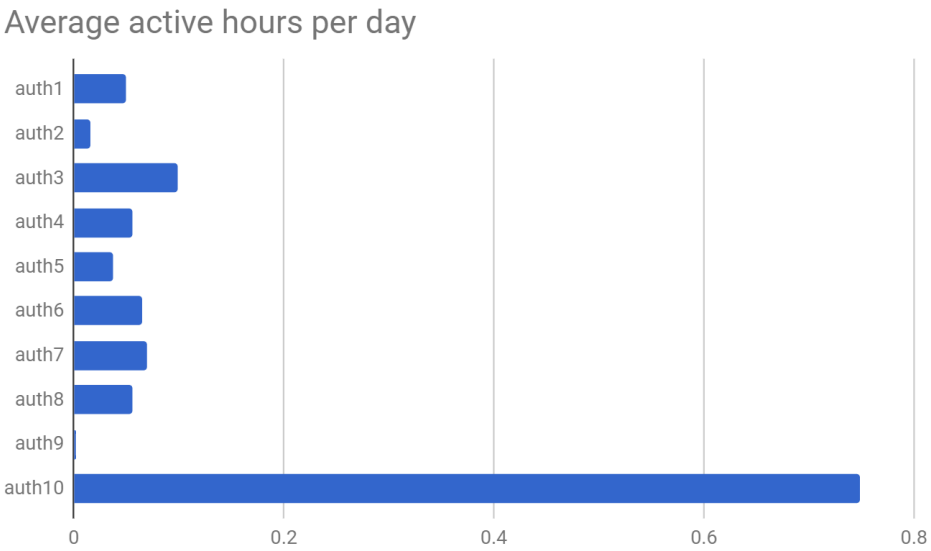

Figure 5 – PD participants average active usage hours per day

Looking at Figure 4, we may categorize PD participants in three categories, i.e. ones that used the system very little (auth2, auth9), users that made moderate use (auth1, auth3, auth4, auth5 auth6, auth7, auth8) and users that made frequent use (auth10). Based on this categorization, the participants: 'auth3', 'auth7' and 'auth10' were selected from the MDA Helllas centre to be investigated further. The next three Sections address the performance of these participants.

a) General Usage Outcomes

The usage primary outcomes were calculated for each of the chosen participants. These outcomes appear in the following tables.

Participant	Active hours per day	Unique sites per day	Keystrokes per day	Click per day	Typing speed per day (seconds per character)
Auth3	0.09	2.21	2.21	5.23	1.25
Auth7	0.06	1.11	10.88	2.02	0.93
Auth10	0.74	9.18	277.47	59.44	2.93

Table 30: PD participants general usage primary outcomes (n=3)

b) Activity in Social Media Sites Outcomes

To calculate the social activity primary outcomes, the activities in social media sites per day were calculated in the same manner as above for five of the most popular social media sites. These outcomes appear in the following table.

Participant	Facebook			Instagram		
	sessions	Time spent	Keystrokes	sessions	Time spent	Keystrokes
Auth3	0.34	0	0	0	0	0
Auth7	0.04	0	0	0	0	0
Auth10	1.81	0.25	27.44	0.1	0	0.68
	Twitter			YouTube		
	sessions	Time spent	Keystrokes	sessions	Time spent	Keystrokes
Auth3	0	0	0	0.5	0.03	0.67
Auth7	0	0	0	0.55	0.03	6.69
Auth10	0	0	0	0.42	0.04	3.23
	Email					
	sessions	Time spent	Keystrokes			
Auth3	0	0	0			
Auth7	0	0	0			
Auth10	0.84	0.06	193.28			

Table 31: PD participants' activity in social media sites primary outcomes (n=3)

It seems that the chosen participants for the PD group hardly used social media sites, except for YouTube. Also, auth10, the participants who used the MAMEM platform the most, used the it for emails and Facebook for considerable durations.

c) Most Popular Websites Outcomes

The outcomes regarding the most visited websites appear In the following tables.

Participant	1st most popular website	sessions	Time spent (hours)	Keystrokes
Auth3	duckduckgo.com	41	0.55	16
Auth7	duckduckgo.com	49	0.78	154
Auth10	accounts.google.com	55	0.17	21

Table 32: PD participants primary outcomes in most popular websites (n=3)

The most popular sites in among the chosen PD participants are search sites and for auth10 - the google account, probably due to the large email activity.

3.2.3 Secondary Outcomes

a) Satisfaction and Perceived Usability

The following table presents descriptive statistics of the SUS and QUEST 2.0 scores that were given to the platform by the PD participants.

	Average	SD
SUS	75.5	13
QUEST 2.0	4.2	0.5

Table 33: PD participants descriptive statistics for the SUS and QUEST 2.0 SCORES (n=10)

The average SUS score given to the MAMEM platform by the PD participants is considered 'above average'. The average QUEST 2.0 score given to the MAMEM platform by the PD participants is also considered 'above average'.

b) Evaluation of Persuasive Design

	Average	SD
The MAMEM system did not scare me at all	1.2	0.42
Operating the MAMEM system made me nervous	4.1	1.72
The MAMEM system made me feel uncomfortable	4.5	2.10
The MAMEM system made me feel uneasy	4.9	1.72

Table 34: PD participants descriptive statistics from the evaluation of persuasive design questionnaire – questions 1-4 (n=10)

Results of questions 1-4 in the persuasive design questionnaire suggest that the PD participants felt quite comfortable with the MAMEM platform.

		Average	SD
I could complete the training tasks using the MAMEM system…	…if there was no one around to tell me what to do.	2.6	3.13
	…if I had just the build-in practice games for practicing	2.9	3.28
	…if someone showed me how to do it first.	9	1.88

Table 35: PD participants descriptive statistics from the evaluation of persuasive design questionnaire – question 5 (n=10)

Results of question 5 suggest that the PD participants think that training games gave a slight advantage over learning how to use the system on their own.

	Average	SD
I had control over using the MAMEM system	4.3	1.64
I have the skills and knowledge necessary to use the MAMEM system	5	1.83
Given the skills and knowledge it takes to use the MAMEM system, it was easy for me to use the MAMEM system	5.5	1.51
My interaction with the MAMEM system was clear and understandable	5.8	1.48
I find the MAMEM system to be easy to use	5.5	1.27
I find it was easy to get the MAMEM system to do what I want it to do	5.6	1.78
I find using the MAMEM system enjoyable	5.2	1.32
The actual process of using the MAMEM system was pleasant	4.5	1.51
I had fun using the MAMEM system	4.7	1.49
I had control over using the MAMEM system	4.3	1.64

Table 36: PD participants descriptive statistics from the evaluation of persuasive design questionnaire – questions 6-14 (n=10)

Results of questions 6-14 in the persuasive design questionnaire show that the PD participants tend to find the MAMEM easy to use and enjoyable.

	Average	SD
The training tasks motivated me to train my MAMEM skills (e.g., focus with my eyes, scroll the screen down, etc.)	5.8	1.48
The games in the training tasks (e.g., collecting points) motivated me to do those tasks	5.7	1.42
I had the feeling that the messages of the MAMEM system were intended for me	4.8	1.55
Assuming I had access to a MAMEM system, I intend to use it	6.1	0.74

Table 37: PD participants descriptive statistics for the evaluation of persuasive design questionnaire – questions 15-18 (n=10)

Results of questions 15-18 in the persuasive design questionnaire show that the PD participants report high motivation of using the system, average levels of personalization, and an average level of intention for using it in the future.

3.2.4 Qualitative Outcomes

a) Participants' Testimonials

The participants were asked to provide their impressions on their experiences with operating the platform during the one month. Their inputs were recapped by the study personnel and summarized or quoted below.

AUTH1	One of the users familiarized with the system very quickly and he is using the system almost daily. Nevertheless, he faced problems when he was trying to focus on the keyboard after using it for a significant amount of time.
AUTH2	She reported that she could use the system easily, although she did not recall correctly some of its functionalities and would like to have a leaflet with instructions during the first days of use. She also reported that some web-pages needed more time than expected to load.
AUTH3	She found it was difficult to use the system as she was not familiar with personal computers. She would like to have a leaflet with specific instructions on how to use the platform as she could not use it on her own and needed the aid of her daughter to do so.
AUTH4	He found the system very useful and easy to use, but faced problems with the eye tracker, having to repeatedly unplug and plug the USB cable.
AUTH5	She found the use of the system straightforward and useful for people that cannot operate a computer with their hands. She found the part of re-calibration when leaving the laptop (e.g. to talk to the phone) tiring and unnecessary.
AUTH6	During the first days he had the laptop but he did not use it as he did not have sufficient time. However, when he started using it on a daily basis he was thrilled and even sent us an email using the system writing about his experience: “ I would like to apologize to the research team for not using the system during the first week. I would also like to thank the team for giving me the opportunity to participate in such an intriguing program aiming to help Parkinsonians. This is the very first message I am sending to you in order to evaluate my progress!”.
AUTH7	He was using the system but only for a few minutes each time. He reported that the eye-tracker crashed several times when using the platform. Furthermore, he found it was difficult to type using the virtual keyboard as the typing speed was faster than expected.
AUTH8	He reported that the more time one spends with the system the easier it gets to use it. He also faced problems with the eye-tracker as the device crashed often.
AUTH9	She did not use the system at all.
AUTH10	He found the system very easy to use as he was already using a computer as part of his occupation. He was the second participant to send us feedback via email while using the platform: “This is the first email I am writing using the MAMEM

	platform! I would like to congratulate and thank the whole team for their efforts and continuous support!".

b) Technical problems

The participants were also asked to report any technical difficulties they encountered while using the platform. The following table presents the technical problems that were reported for each participant.

AUTH1	The participant was annoyed by the process of calibrating the eye-tracker. He also mentioned that the eye-tracker crashed frequently, meaning that he had to re-plug the eye-tracker to the USB port to fix it.
AUTH2	No problems were reported.
AUTH3	The participant had difficulties on calibrating the eye-tracker. The system was unable to play some of her favourite online games.
AUTH4	The participant had difficulties on calibrating the eye-tracker. He could not type very efficiently so typing long text was avoided. The participant also mentioned that the eye-tracker crashed frequently, meaning that he had to re-plug the eye-tracker on the USB port to fix it.
AUTH5	The participant mentioned that the system was running slow. The PD dashboard score percentages were not improving after using the system. She had difficulties on calibrating the eye-tracker. She also had problems on accurately making a selection using the eye-tracker.
AUTH6	No problems were reported.
AUTH7	The participant had problems on accurately making a selection using the eye-tracker. He also had problems with the language (English)
AUTH8	The participant mentioned that the eye-tracker crashed frequently, meaning that he had to re-plug the eye-tracker on the USB port to fix it.
AUTH9	No problems were reported.
AUTH10	The participant mentioned that the eye-tracker crashed frequently, meaning that he had to re-plug the eye-tracker on the USB port to fix it.

c) Experimenters' Impression from the Participants

In this part, we bring the qualitative impression of the experimenter from the participants.

AUTH1	He was among the friendliest participants and particularly excited about his participation in the experiments. Although he is one of the most aged subjects he was interested in topics regarding technology. However, these facts were not evident during the installation day due to side effects of his pharmaceutical treatment, as he informed us later.
AUTH2	She was very stressed and was always afraid of making a mistake.
AUTH3	She was rather happy participating in the experiments. She was primarily using a tablet for playing games. The platform was not optimised for gaming and this was a disadvantage for the whole experience. As it was expected, her experience with technology was limited and although she could operate the system with ease when someone was instructing her she didn't seem to understand all the aspects during the training.
AUTH4	He was positive on using the platform. He also agreed to participate in an extra series of experiment regarding MM-Tetris.
AUTH5	The severity of her symptoms was extremely light and she found no particular use of the platform since she could operate a conventional keyboard with ease.
AUTH6	He was very excited with the system. He was extremely familiar with personal computers and therefore he didn’t face any difficulties.
AUTH7	The patient was very eager to use the platform, but probably due to his old age he had difficulties on completing several training tasks. He also seemed to forget some of the functionalities of the system easily, so he requested a printed copy that explains the functionality of each button.
AUTH8	He had difficulties in operating the eye tracker. Generally, he seemed to appreciate the platform.
AUTH9	She seemed to be happy with the system although her interests did not match with those that the platform is aiming for. However, she informed us by the end of experiments that she hasn’t used the system at all.
AUTH10	He was thrilled by the potential of the platform and praised our efforts. However, he found the platform rather tiring and did not fully engage during the demonstration that accompanied the training.

d) 2-week Follow-up

	Average	SD

On a scale of 10 to 1, how satisfied are you using MAMEM, up to this point? Where 10 means 'very satisfied' and 1 means 'not at all satisfied'	8	1.6
In comparison to the previous digital device, how satisfied are you with MAMEM, on a scale of 1 to 5, where 5 is 'by comparison more satisfied' and 1 is 'by comparison not at all satisfied'	3.5	1.06
Now that you have tried MAMEM for 2 weeks, how probable is it that you would recommend it to a person in your condition on a scale of 10 'would definitely recommend' to 1 'would not at all recommend'?	9.25	1.03

Table 38: PD Participants' answers to the 2-week phone call questionnaire (n=10)

In the two-week call, the PD participants report high satisfaction of using the MAMEM platform, that they are satisfied with it in the same level as their previous digital device and that they would definitely recommend it to other people in their condition.

e) Case-Study Analysis

A case study analysis of an PD participant reporting high satisfaction with MAMEM

Demographics	A 53-year-old man suffering from Parkinson's disease since his 42nd year. He is working full time, as a Fine Arts University Professor. He is married with two children.
Mobility status	Currently he is experiencing severe tremor in his hands, which is exacerbated whenever he is experiencing tension, fatigue, or anxiety. He is also experiencing bradykinesia (slow movement, making simple tasks difficult and time consuming). He has impaired posture and balance and is also experiencing muscle stiffness.
History with digital device use	He is a long-time user of digital devices, and for most of his professional life it has been important to carry out work on the computer.
Current digital device used	He is using a digital device, mostly a desktop computer, for a minimum of 5 hours a day. His efficiency at work depends wholly on using the computer well, and with speed. He organizes class notes, research projects, and lecture presentations, correspondence with colleagues, article writing, online research, and several other organizational tasks. His ability to use the computer with ease and speed has been significantly impaired due to his condition.
Learning to use the device	He was very receptive to MAMEM and was able to get used to it quickly. He was able to swiftly switch from his own device to using MAMEM for the majority of the tasks he carries out digitally. He found MAMEM very easy to learn and implement.
The experience of MAMEM over time	Over time he expressed high satisfaction with MAMEM because it facilitated greatly his use of the computer, allowing him to re-experience what it is like to be using the computer effortlessly. After a

	few days he was able to use MAMEM smoothly.
Range of MAMEM usage	This participant mentioned that he was able to carry out mostly all-important tasks useful to his day-to-day activities and obligations. He mostly used the editor, search function, but also used Facebook using MAMEM, too. For the duration of the trial he replaced his current computer completely with the use of MAMEM.
Critical satisfaction factors	This participant mentioned that the difference MAMEM made in the way he uses the computer was twofold: 1) He was able to carry out his regular tasks with more ease, and with much less frustration caused by slow movement. 2) He was able to not only use the computer more effortlessly but also faster, so that for the amount of time he spent on the computer, he was able to make better use of his time, and achieve more for the time he used the computer.
Dissatisfactions with MAMEM	He did not express dissatisfaction. Any crashes he encountered he attributed to the "baby stage" of the technology, so he tolerated them.
Core learnings from this case	When a participant has experienced a significant "before" and "after" the disease change in their using of digital devices, they are very eager to cooperate with a new technology, in order to recapture former ease and speed, stolen by their symptoms. In addition, when the use of a digital device is intimately connected to one's ability to perform at work there are high expectations of the technology, and the more the person derives satisfaction and recognition at work, the more they seem to be eager to cooperate with the technology so as to assimilate it seamlessly.
Future perspectives	Parkinson's disease sufferers tend to be older and sometimes awed by technology to the point of becoming resistant to its adoption. This seems to be less the case when the person is going through his illness in a positive work and family environment, as is evident in this case. MAMEM needs to take this into consideration, ensuring that the process of learning and getting used to MAMEM is simple, easy and encouraging. Persuasion technology will need to be further employed and studied to that effect.

A case study analysis of an PD participant reporting lower satisfaction with MAMEM

Demographics	A 50-year-old male, suffering since his 44th year from Parkinson's disease. He is an employed as a wholesale salesman.

Mobility status	The participant suffers from fairly severe tremor in the hands, slow movement (bradykinesia) and muscle stiffness. His tremor is exacerbated by his intense anxiety about his employment. He feels that in recessionary Greece there is strong competition for a job like his, among younger and healthier people. He is probably an efficient salesman; therefore, he does retain his employment. However, he lives with ongoing fear of being fired, given that he is not eligible yet for pension.
History with digital device use	The use of the computer is not very extensive but is nevertheless important for his work. He needs to write work related emails on a daily basis, and he also carries out some e-banking tasks.
Current digital device used	He uses a desktop/laptop device on a daily basis.
Learning to use the device	This participant expressed frustration during the learning period. He expressed that the device is not responsive; he makes too many mistakes using it.
The experience of MAMEM over time	This participant expressed an overall negative attitude to MAMEM and his complaints were: 1) It crashes too often 2) He could not use it smoothly not making mistakes 3) At the end of its use he felt tired
Range of MAMEM usage	He sought to make use of MAMEM for his regular daily activities, which are work related.
Critical satisfaction factors	He grew frustrated during the learning and adoption process.
Dissatisfactions with MAMEM	This participant is the case of a person already feeling vulnerable in his work environment, due to his symptoms. He has become comfortable with his current device to the point of using it for work slowly, but efficiently and without mistakes. To become able to make the best use of MAMEM, improving the ease and speed of his computer use, he would need to tolerate a learning stage, where mistakes are a given, and part of the learning curve. In his case, and given his work insecurity, he was completely intolerant of the learning process and the mistakes involved in it.
Core learnings from this case	The insight to be gleaned from this case study of a less enthusiastic MAMEM user is: it is important to understand the mistake toleration level involved in computer use. The adoption process then needs to take that into consideration

	and advise the beginner user accordingly.
Future perspectives	Future users need to understand that the learning process is instrumental, and though it may be painstaking initially, it is the stage that will be followed by smooth and seamless use. Future users need to understand that the use of MAMEM will be rewarding, improving use of digital devices, after a learning period is completed, where its use may not be as smooth.

3.2.5 Multi-modal interfaces

Results for PD3 participant.

Experience with the assistive devices	As we have already stated the tremor effect was rather intense. Therefore, the quality of recorded EEG signals was extremely low which constituted a major barrier to the whole experimental process. Her interaction with the eye-tracker and the GSR appeared to be seamless.
MM-Tetris	
User motivation over time	Initially the participant seemed highly motivated since she was mainly interested in playing games (especially those that are related with mind skills). However, she was unfamiliar with the Tetris game, probably due to the old of her age, and gradually her interest in learning a totally new game was weakening.
Experience with the software	The participant did not understand the instructions very quickly. The game purpose seemed “fuzzy” (judging by her performance) and could not operate the game elements properly.
Technical problems	No technical problems.
Performance of the system	The classification accuracy of the EEG also was very poor, probably due to the artifacts that contaminated the EEG signal. Additionally, although she had the potential to operate the eye-tracker decently, which is inferred by her performance with system during the training and web browsing tasks, her performance in the MM-Tetris was very poor which is attributed to the lack of experience with the game.
ErrP gaze keyboard	
User motivation over time	The ErrP experiment was performed after the MM-Tetris, followed by a short break, and the participant was already haggard.
Experience with the software	She was unfamiliar with the positioning of the keys over the screen keyboard layout and hence could not operate the modified gaze-based keyboard, that was faster and lacked the continuous visual

	indication about the current gazing location. Despite her credible efforts, she could not complete the task.
Technical problems	No technical problems.
Performance of the system	The experiment was interrupted.

Results for the PD5 participant:

Initial impression of the experimenter	The participant was in a good condition and experienced tremor only in cases of high anxiety. He was eager to participate in the study as he realized its potential and the impact it could have on his everyday life.
Experience with the assistive devices	This was his first experience with an EEG scanner, nevertheless he felt comfortable during the cap placement and seemed to enjoy the whole process. He even asked us to take a couple of pictures while wearing the EEG cap, in order to "capture the moment" as he said.
MM-Tetris	
User motivation over time	The participant was highly motivated during the whole course of the experiment. There were times that he could not rotate the tetrimino that increased his anxiety and tremor but he was reassured that this was not the outcome of his faulty behavior and that this is a common trend for naïve BCI users. This led to a decreased anxiety over time that resulted in better manipulation of the tetriminos.
Experience with the software	The participant was familiar with the game and it was easy for him to realize the transition to the multimodality of MM-Tetris.
Technical problems	No technical problems.
Performance of the system	He could control the tetrimino placement with the eye tracker pretty well. The rotation of the tetriminoes was not always the one he originally aimed, but there were several times that he reached to the correct rotation. As a result, he managed to "clear" 4 lines, a quite impressive outcome for a first-time user.
ErrP gaze keyboard	
User motivation over time	The participant was eager to use the gaze keyboard, until he realized he should type in English as he did not speak the language fluently. As a result, he found the spelling part really challenging and made several errors that he did not comprehend.
Experience with the software	As previously described, the participant made a lot of mistakes during the spelling process but could not realize them. As a result,

	we used calibration data from previous studies in order for the classifier to be trained properly.
Technical problems	No technical problems.
Performance of the system	During the typing task using the ErrP gaze keyboard, the system could detect a high proportion of the identified by the user mistakes, providing promising results. Nevertheless, there were a few cases that the system deleted letters that were not supposed to be removed.

3.3 SCI Participants' Results

3.3.1 Demographical, Clinical and Computer Usage Data

In the next tables we report the demographic and clinical data of the SCI participants.

a) Demographical Data

	N	% / Average (SD)
Age	10	38.1 (10.7)
Education years	10	13.1 (2.84)
Gender		
Male	10	100%
Female	0	0%
Marital Status		
Married	3	30%
Single	7	70%
Children No.		
0	7	70%
1	1	10%
2	1	10%
3	1	10%
Working		
Full-time	1	10%
Part-time	3	30%
No	6	60%
Hand preference		
Right	9	90%
Left	1	10%

Table 39: Demographic characteristics of the SCI participants (n=10)

Looking at the demographic data of the SCI participants, it is possible to see that all of them are males, most of them are not married and that most of them are not working.

b) Clinical Data

	N	% / Average (SD)
Diagnosis		
C2	2	20%
C3	1	10%
C4	4	40%
C5	2	20%
C6	1	10%
Reason of SCI		
Transport	5	50%
Fall	1	10%
Non-traumatic	4	40%
Years with a SCI	10	12.9 (7.7)
Use wheelchair		
Yes	10	100%
Wheelchair type		
Motorized	8	80%
Regular	2	20%
Move yourself		
Yes	9	90%
Have a car		
Yes	8	80%
Drive		
Yes	7	70%
Hours in bed per day	10	12 (3.5)
Months in rehabilitation	10	7.5 (2)
Financial support		
Ministry of defence	2	20%
Social security	8	80%
Family	1	10%
Work	1	10%
Pension	1	10%

Table 40: Clinical characteristics of the SCI participants (n=10)

	Tongue		Jaw		Neck		Shoulders		Arms		Elbows		Wrists		Hands		Fingers	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
No Symptom	10	100%	10	100%	10	100%	5	50%	1	10%	4	40%	2	20%	0	0%	0	0%
Partial	0	0%	0	0%	0	0%	5	50%	9	90%	5	50%	6	60%	2	20%	2	20%
Complete	0	0%	0	0%	0	0%	0	0%	0	0%	1	10%	2	20%	8	80%	8	80%

Table 41: Distribution of partial or complete bradykinesia/numbness/immobility among the SCI participants (n=10)

The clinical data of the SCI participants indicates that most of them use a motorized wheelchair, move themselves, have a car and drive. Also, they spend many hours a day in bed. Finally, all of them suffer from partial and complete bradykinesia in body parts that are necessary for computer operation.

c) Computer Usage Data

The following table present the SCI participants' perceived impact of the disability on their social lives according to the question: "How is your social life affected by your disability?".

	frequency	percent
My social life is normal	4	40%
There is no significant effect on my social life apart from limiting energetic aspects, such as dancing	2	20%
My social life is restricted, and I do not go out as often	4	40%
My social life is restricted to my home	0	0%
I have no social life and feel lonely	0	0%

Table 42: SCI participants' perceived impact of their disability on their social lives (n=10)

Most of the SCI participants report that their disability has a significant effect of their social lives. The following table present the participants' perceived impact of the disability on outdoor mobility.

	frequency	percent
I travel frequently for needs / pleasure	7	70%
I travel sometimes	2	20%
I travel very rarely and only when there is an absolute need	1	10%
I cannot travel and must stay home	0	0%

Table 43: Impact of the disability on SCI participants' mobility outdoors (N=10)

Most of the SCI participants report normal mobility of a small limitation in their mobility. The following table presents the computer use habits of the participants.

	N	% / Average (SD)
Digital devices owned		
Desktop computer	6	60%
Laptop computer	9	90%
Tablet	5	50%
Smartphone	10	100%
Use a computer		
Yes	8	80%
Average hours of computer use per day	8	3.9 (3.6)
Years of experience of operating computers	8	21 (4.7)
Operating system		
Windows	8	80%
Apple OS	1	10%

Table 44: computer use habits of the SCI participants (N=10)

The SCI participants own many digital devices. All of them report having a smartphone. Almost all of them use computers and those who do, use them for significant durations and report having many years of experience using them. The participants were asked to report which digital device they used the most. The following figure presents their answers.

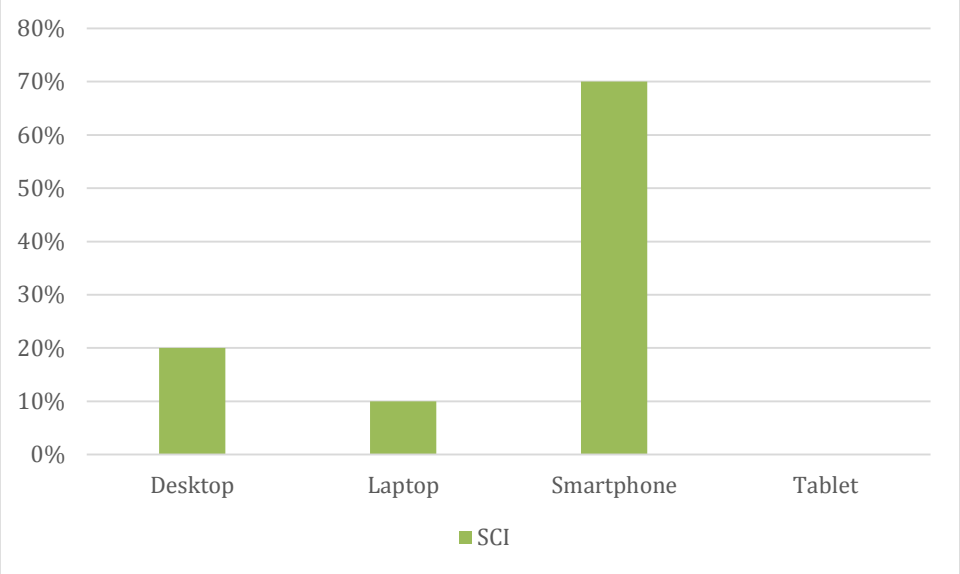

Figure 6 - Digital device use patterns by the SCI participants (n=10)

The vast majority of the SCI participants report using their smartphone the most. The following table presents the answers for the question: "To what extent do your physical symptoms impair your ability to use the computer as extensively and as widely as you might like?".

	frequency	percent
My symptoms do not interfere at all with my ability to use the computer	0	0%
My symptoms interfere a slightly	1	12.5%
My symptoms interfere fairly much	2	25%
My symptoms interfere very much	5	62.5%
I am not sure/I do not know	0	0%

Table 45: the SCI participants physical symptoms' perceived effect of on computer operation (n=8)

Most of the SCI participants report a large interference of their clinical condition on their computer use. The following tables present the main computer uses of the participants and the main applications that the participants reported using.

	frequency	percent
Social participation (Facebook, forums, etc.)	6	75%
Productive activities (writing, editing, etc.)	5	62.5%
Study (on-line courses, articles, etc.)	5	62.5%
Games	1	12.5%
Recreation (movies, music, crossword puzzles, blogs, etc.)	8	100%
Communication (email, Skype, etc.)	5	62.5%
Activities of daily living (purchases, payments, bank, etc.)	6	75%
Information (Wikipedia, governmental sites, news, maps, etc.)	7	87.5%
Other	1	12.5%

Table 46: Main computer uses of the SCI participants (n=8)

It seems that the most important computer uses of SCI participants are recreation activities and information.

	frequency	percent
Internet browser	5	62.5%
Email client	4	50%
Word processor	5	62.5%
Audio/video/image applications	4	50%
Spreadsheets (e.g. Excel)	5	62.5%
Computer games	1	12.5%
Presentation software	3	37.5%
Programming/database	0	0%
Media editing applications	2	25%
Other	0	0%

Table 47: Main computer uses of the SCI participants (n=8)

The SCI participants seem to use the computers for various uses with no clear pattern. internet browsing seems much less important than in other cohorts, perhaps due to the increased usage of smartphones.

3.3.2 Primary Outcomes

The following figure presents the average active usage hours per day for SCI participants.

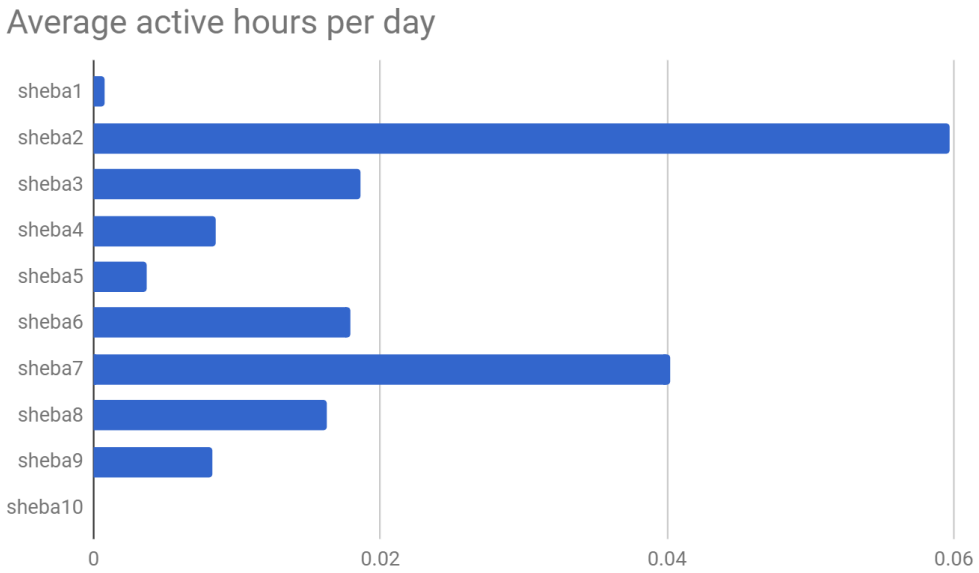

Figure 7 – SCI participants average active usage hours per day

Looking at Figure 6, we may categorize SCI participants in three categories, i.e. ones that used the system very little (sheba1, sheba5, sheba10), users that made moderate use (sheba3, sheba4, sheba6, sheba8, sheba9) and users that made frequent use (sheba2, sheba7). Based on this categorization, the participants: ' sheba2', ' sheba3' and ' sheba7' were selected from the Sheba centre to be investigated further. The next three Sections address the performance of these participants.

a) General Usage Outcomes

The usage primary outcomes were calculated for each of the chosen participants. These outcomes appear in the following tables.

Participant	Active hours per day	Unique sites per day	Keystrokes per day	Click per day	Typing speed per day (seconds per character)
Sheba2	0.05	1.03	7.25	2.25	0.51
Sehab3	0.01	0.27	0.27	0.4	0.23
Sheba7	0.04	0.77	16.88	4.65	0.83

Table 48: PD participants general usage primary outcomes (n=3)

b) Activity in Social Media Sites Outcomes

To calculate the social activity primary outcomes, the activities in social media sites per day were calculated in the same manner as above for five of the most popular social media sites. These outcomes appear in the following table.

Participant	Facebook			Instagram		
	sessions	Time spent	Keystrokes	sessions	Time spent	Keystrokes
Sheba2	0	0	0	0	0	0
Sehab3	0	0	0	0	0	0
Sheba7	0.34	0	10.6	0	0	0
	Twitter			YouTube		
	sessions	Time spent	Keystrokes	sessions	Time spent	Keystrokes
Sheba2	0	0	0	0.38	0.02	3.35
Sehab3	0	0	0	0.0.3	0	0.27
Sheba7	0	0	0	0	0	0
	Email					
	sessions	Time spent	Keystrokes			
Sheba2	0	0	0			
Sehab3	0	0	0			
Sheba7	0	0	0			

Table 49: SCI participants' activity in social media sites primary outcomes (n=3)

The activity in social media sites data for chosen participants of the SCI group suggest that they rarely used it for these purposes.

c) Most Popular Websites Outcomes

The outcomes regarding the most visited websites appear in the following tables.

Participant	1st most popular website	sessions	Time spent (hours)	Keystrokes
Sheba2	duckduckgo.com	53	0.39	117
Sheba3	clarin.com	6	0.18	0
Sheba7	duckduckgo.com	27	0.11	4

Table 50: SCI participants primary outcomes in most popular websites (n=3)

The most popular sites in among the chosen SCI participants are search sites.

3.3.3 Secondary Outcomes

a) Satisfaction and Perceived Usability

The following table presents descriptive statistics of the SUS and QUEST 2.0 scores that were given to the platform by the SCI participants.

	Average	SD
SUS	73.33	15.81
QUEST 2.0	4.33	0.48

Table 51: SCI participants descriptive statistics for the SUS and QUEST 2.0 SCORES (n=9)

The average SUS score given to the MAMEM platform by the SCI participants is considered 'average'. The average QUEST 2.0 score given to the MAMEM platform by the SCI participants is also considered 'above average'.

b) Evaluation of Persuasive Design

	Average	SD
The MAMEM system did not scare me at all	1.85	1.86
Operating the MAMEM system made me nervous	6	1.15
The MAMEM system made me feel uncomfortable	5.57	1.39
The MAMEM system made me feel uneasy	6.28	0.75

Table 52: SCI participants descriptive statistics from the evaluation of persuasive design questionnaire – questions 1-4 (n=7)

Results of questions 1-4 in the persuasive design questionnaire suggest that the SCI participants felt quite comfortable with the MAMEM platform.

		Average	SD
I could complete the training tasks using the MAMEM system…	…if there was no one around to tell me what to do.	4.57	2.99
	…if I had just the build-in practice games for practicing	6.14	3.07
	…if someone showed me how to do it first.	8.28	2.56

Table 53: SCI participants descriptive statistics from the evaluation of persuasive design questionnaire – question 5 (n=7)

Results of question 5 suggest that the SCI participants think that training games gave a small advantage over learning how to use the system on their own.

	Average	SD
I had control over using the MAMEM system	2.57	1.27
I have the skills and knowledge necessary to use the MAMEM system	3.14	1.86
Given the skills and knowledge it takes to use the MAMEM system, it was easy for me to use the MAMEM system	2.86	1.07
My interaction with the MAMEM system was clear and understandable	2.57	0.98
I find the MAMEM system to be easy to use	2.71	1.50
I find it was easy to get the MAMEM system to do what I want it to do	3.29	1.11
I find using the MAMEM system enjoyable	2.86	0.69
The actual process of using the MAMEM system was pleasant	3.57	1.51
I had fun using the MAMEM system	3.43	1.51
I had control over using the MAMEM system	2.57	1.27

Table 54: SCI participants descriptive statistics from the evaluation of persuasive design questionnaire – questions 6-14 (n=7)

Results of questions 6-14 in the persuasive design questionnaire show that the SCI participants tend to find the MAMEM system not very easy to use and not very enjoyable.

	Average	SD
The training tasks motivated me to train my MAMEM skills (e.g., focus with my eyes, scroll the screen down, etc.)	4.14	1.21
The games in the training tasks (e.g., collecting points) motivated me to do those tasks	4	1
I had the feeling that the messages of the MAMEM system were intended for me	3	1.41
Assuming I had access to a MAMEM system, I intend to use it	3.14	1.77

Table 55: SCI participants descriptive statistics for the evaluation of persuasive design questionnaire – questions 15-18 (n=7)

Results of questions 15-18 in the persuasive design questionnaire show that the SCI participants report average levels of motivation of using the system, average levels of personalization, and an average level of intention of using it in the future.

3.3.4 Qualitative Outcomes

a) Participants' Testimonials

The participants were asked to provide their impressions on their experiences with operating the platform during the one month. Their inputs were recapped by the study personnel and summarized or quoted below.

Sheba1	No testimonial to report.
Sheba2	The participant said that he found the MAMEM platform to be a great tool for people with disabilities and useful for his needs.
Sheba3	This participant said that he liked the system and thought it can be very beneficial for people with disabilities. He also said that the vice-prime minister of Argentina was very enthusiastic about it.
Sheba4	He said that in the beginning of the study he thought that he will use it a lot but he encountered many problems in operating the eye-tracker and now he is not so sure that every person can use it.
Sheba5	Sheba5 uses computers for many hours a day and indeed has some difficulties in operating them so he was excited to participate in the study and adamant in his efforts to use the MAMEM platform. However, he encountered many problems in operating the eye-tracker and in the end of the study he was not very positive about it.
Sheba6	This participant was not very communicative during the study and most of the communication with him was done thorough his care taker who said that this participant is depressed and that he hardly does anything during the day other than watching movies and TV shows. Also, he does not have any social life.
Sheba7	He said that he does not use computers that often, but when he does it is for online shopping and other functional activities, not so for social participation. Therefore, he was positive in that he found a better way to perform these activities, but he does not need the MAMEM platform for anything else.
Sheba8	Sheba8 said that he already has a laptop that he uses for work, social participation and other needs and that during the years he had found a good-enough solution for him to operate it. Therefore, the MAMEM platform must provide a much better solution in order for him to change his way of operating computers and at this point it does not.
Sheba9	He said that he does use the internet and participate in social networks since he did this before his accident, and it is a large part of his life, but these days he uses his smartphone for these activities and he does not think that the MAMEM platform will provide a better solution for him, one that will make him abandon the smartphone. At this point it does not.
Sheba10	This participant said in the beginning of the study that he hardly uses computers

	and surfs the internet, mainly due to his medical condition. When he was introduced to the system he showed hope that by using the MAMEM platform he will start using it and will participate more in social networks. Also his family was optimistic about this. However, in the end of the study it came clear that it did not, and the participant said that he had gotten used to his situation and perhaps he has given up on this aspect in his life.

b) Technical problems

The participants were also asked to report any technical difficulties they encountered while using the platform. The following table presents the technical problems that were reported for each participant.

Sheba1	There were no technical problems in the installation process. A proper operation location was located. However, the participant was not very cooperative with the study personnel and not completely attentive on the explanations on how to operate the platform.
Sheba2	There were no problems in the installation process. A proper operation station was located.
Sheba3	There were no problems in the installation process. A proper operation station was located.
Sheba4	With this participant, there were many difficulties in the installation process. Mainly, trying to find an appropriate operating location, one that would allow the participant to put the laptop in a sufficient height and angle, and also allow him to go under it with the wheelchair. The participant said that he spends most of the day in bed and asked whether it will be possible to operate the platform from there. He was informed that it will not be possible. Therefore, he promised that later we he will attempt to acquire a proper table. Also, connecting to WIFI was rather difficult so it was necessary to connect to the neighbour's WIFI with his permission. During the two weeks after the installation, the participant called several times and said that he cannot operate the system since has trouble operating the eye tracker due to constants disconnections. He also mentioned that he did not yet get a proper operating table and was trying to operate while the laptop was sitting on a cupboard and he was sitting next to it while looking sideways. In these conversations, the participant was told that he must get a proper operation table or shelf as soon as possible and that if he does not, the system will be taken away from him. Two weeks after the installation, in the phone call, he was asked

	whether there was change in the situation. There was not. Therefore, in consultation with the Sheba study's PI, it was decided to remove the system from this participant. A few days later, the experimenter arrived to remove it, but the participant implored that it will be left at his home and he promised to get an adequate operating table in the next couple of days. After a long deliberation, the experimenter agreed to this. During the following two weeks, the participant was contacted several times by phone and by WhatsApp and was asked whether something had changed but nothing did. In several occasions, the participant did not answer and did not call back.
Sheba5	in the first visit to the participant's home, he was feeling sick and could not leave his bed and move to his wheelchair. Since the experimenter lives rather close to his home, it was decided that the system will be installed at the current visit, and once he feels better, the experimenter will return in the evening and perform all the first visit activities. A few days later, in a phone call, the participant informed that he feels better and on that evening the experimenter went to his home to perform the first visit activities. Once arrived, the experimenter saw that the participant was still feeling 'under the weather' but decided to continue anyway due to the timetable of the trials. The experimenter also noticed that in this case as well, the conditions in this participant's home do not fully allow the operation of the eye tracker due to a lack of a proper table in the right height and angle that can enable the participant to go under it with the wheelchair. During the following two weeks, the experimenter performed several phone calls and WhatsApp conversations with the participant in which he was asked whether he is able to operate the system. The participant said that he cannot successfully operate the system since he cannot operate the eye-tracker properly. Therefore, after two weeks, it was decided to remove the system from the participants' home. Though terminated early, the participant was not considered a drop-out since he cooperated with the study protocol, despite hardly using the system.
Sheba6	There were no problems in the installation process. A proper operation station was located.
Sheba7	There were no problems in the installation process. A proper operation station was located.
Sheba8	There were no problems in the installation process. A proper operation station was located.
Sheba9	The installation process in this participant's home was successful, although a

	proper operation station was not easily located. Locating one took a large portion of the visit since it included calling the home owner and trying to locate an appropriate spot and table. In this case, in light of past experience with other participants, it was decided beforehand to devote much effort to this part.
Sheba10	There were no problems in the installation process. A proper operation station was located.

c) Experimenters' Impression from the Participants

In this part, we bring the qualitative impression of the experimenter from the participants.

Sheba1	This participant did not seem to cooperate from the first visit. He did not seem interested in the study and was generally not coherent, perhaps due to medication effects. Later he sometimes did not answer the phone and seemed like he was avoiding the experimenter. The general feeling was that he did not want to participate in the study. A few days after the installation, the participant was contacted over the phone and was asked whether he is able to operate the system. The participant said that he has a toothache that prevents him to do anything. In this conversation, he was told that if he does not intend to use the system, it will be taken away from him and moved to another person that could benefit from it. He agreed to this, but it took a few more days to coordinate a time to pick it up. At this point, the participant was removed from the study due to lack of motivation to participate in the study and lack of cooperation with the study personnel.
Sheba2	The participant was highly cooperative and enthusiastic to participate in the study. It seemed that he enjoyed using the MAMEM platform.
Sheba3	In the beginning of the study the participant was very cooperative. Before beginning the actual participation in the study, this participant reported, in the pre-screening meeting, that around two weeks after the installation, he is planned to fly to Argentina for 5 weeks in order to meet with the vice-president of Argentina to provide her advice regarding a national plan to increase accessibility to disabled people all across the country. Since this period is longer than the one-month participation period, an approval was needed from for his participation from the project manager, where it was suggested that if the participant could expose the MAMEM platform to the vice president and to her team, it could be a nice addition to the project dissemination activity. However, after the participant's departure, he did not answer the emails or WhatsApp conversations. Later he reported that he had medical complications in Argentina and this is why

	he was not available and hardly used the system.
Sheba4	This participant seemed cooperative at first but later it seemed that he does not want to find a solution for the operating conditions that prevented hip to operate the system successfully.
Sheba5	This participant showed some interest in the study in the beginning but later showed little cooperation with finding proper operating conditions. When the experimenter arrived at his home to remove the system prematurely, the participants was not pleased and promised to try and find an operating solution. However, due to his lack of cooperation and in order for another participant to be able to use the platform it was decided to go ahead and remove the system.
Sheba6	The communication with this participant was done only through his caretaker since the participant does not have a phone. In the first visit he seemed interested in the study although he reported that he does not use the computer and the internet other than watching movies. This participant also seemed a bit depressed due to his medical condition.
Sheba7	Sheba7 is a middle-aged man in pension who is mostly home. He said that he uses computer quite a lot, mostly for online shopping. He was extremely cooperative and it looked like he really wanted to participate in the study.
Sheba8	Sheba8 works with computers and therefore said that it seems that he will use the platform since it looks like it will offer a better operation solution than his current system. However, later he said that he found out that it does not offer a better solution and therefore he preferred to use his old system. He was very honest about this.
Sheba9	This participant is a young man who got hurt not long ago. Before the accident he used smartphones and now he can still operate them using the touch. This is why he probably did not use the platform. Due to his age and the social networks that he is part of in his phone, it seemed like he was not very interested in the MAMEM platform.
Sheba10	This participant notified the experimenter that he has no use of computers, although he owns one, and does not know if the MAMEM platform will change this. Indeed, the results show that he did not use the system at all. He also was very honest about this.

d) 2-week Follow-up

	Average	SD
On a scale of 10 to 1, how satisfied are you using MAMEM, up to this point? Where 10 means 'very satisfied' and 1 means 'not at all satisfied'	6	1.8
In comparison to the previous digital device, how satisfied are you with MAMEM, on a scale of 1 to 5, where 5 is 'by comparison more satisfied' and 1 is 'by comparison not at all satisfied'	3.25	1.3
Now that you have tried MAMEM for 2 weeks, how probable is it that you would recommend it to a person in your condition on a scale of 10 'would definitely recommend' to 1 'would not at all recommend'?	6.9	2.2

Table 56: SCI Participants' answers to the 2-week phone call questionnaire (n=9)

In the two-week call, the PD participants report average levels of satisfaction from using the MAMEM platform, that they are satisfied with it in the same level as their previous digital device and that they would recommend it to other people in their condition.

e) Case-Study Analysis

A case study analysis of an SCI participant reporting high satisfaction with MAMEM

Demographics	Sheba2 is a 39-year-old male. Married with 3 children. He has 12 years of education and is a business man (owns a few businesses).
Mobility status	Sheba2 uses a motorized wheelchair. He owns a car and able to drive it. He travels abroad frequently. He spends ~hours a day in bed.
History with digital device use	Sheba2 has a desktop computer and a smartphone. He has had them both for a few years. He uses them both but not in the same frequency – he uses the smartphone a lot but hardly uses the laptop. He had a upside down mouse to operate the desktop but stopped using it because it caused pain in the shoulder.
Current digital device used	Sheba2 currently uses his smartphone for many hours a day. He operates it using touch. He is very happy with it although he cannot do certain things with it. He says that the its' advantages overlay its disadvantages. Its main advantages are that its small and light, available on him at all times and he can operate it with touch which does not necessitate delicate use of the fingers.
Learning to use the device	Sheba2 says that he feels that the short operating course that was done in the first visit with the experimenter was good and enough to know how to operate the platform. He also feels that during the one month with the platform he got better in using it.
The experience of MAMEM over time	Sheb2 says he feels that as time went by, he has gotten used to operating the platform. Also, he says that the experience with the system has gotten better over time.
Range of MAMEM	Sheba2 says that he used the MAMEM platform to go to social

usage	networks sites such as YouTube and Facebook. He also used it for searching various things on the internet in Google and for other useful productive purposes such as banks information, email.
Critical satisfaction factors	For sheba2, the critical satisfaction factors are the ease of operation and the usefulness of the assistive device. In that sense, the MAMEM platform is useful and easy to operate so he was satisfied with it.
Dissatisfactions with MAMEM	The only thing shea2 could think about that he was dissatisfied was the calibration process that was a bit annoying at times.
Core learnings from this case	Sheba2 says that he learned that technology gets better and better over time and better solutions and assistive devices continue to come out. It is encouraging.
Future perspectives	Sheba2 plans to buy a new laptop and to try to operate it at first using a regular mouse although the difficulties. Later, he may buy an eye tracker and use it with the MAMEM platform.

A case study analysis of an SCI participant reporting lower satisfaction with MAMEM

Demographics	Sheba10 is a 24-year-old young man who has a high spinal cord injury. He lives with his parents, not married and has no children. He does not work and does not get out a lot.
Mobility status	Sheba10 must use a motorized wheelchair to move around. He spends most of his day in bed and needs assistance to get in and out of the bed. When he needs to go out of the house he can drive but prefers someone else to drive him.
History with digital device use	Sheba10 has had a Smartphone for the last 7 years and a laptop computer and desktop computer for the last 15 years.
Current digital device used	Sheba10 uses his smartphone for ~1.5 hours a day. He does not use his desktop and laptop computer at all although he has assistive devices that allow him to use them.
Learning to use the device	Sheba10 feels like he got a good training course by the experimenter on how to use the MAMEM platform in the first visit. When he was alone and tried to do the training games, he was able to remember how to use it.
The experience of MAMEM over time	Sheba10 hardly used the system over time. Also, he was sick for a large part of the month with the system. When he did use it, it was only for the training games and then he found it a bit tiresome.
Range of MAMEM usage	The only use for Sheba10 was his attempt to attempt to complete the training games. He did not use it for internet at all.
Critical satisfaction	Sheba10 says that the Smartphone provides all he needs in terms of

factors	computer and internet needs which is not a lot anyway. In this context, his satisfaction factors are relatively very low.
Dissatisfactions with MAMEM	Sheba 10 was not dissatisfied with the MAMEM platform. On the contrary, he liked the idea and thought it could be a great solution for other people with a SCI. however, he himself does not like computers and has no real incentive to use them.
Core learnings from this case	Nothing to be mentioned.
Future perspectives	Nothing to be mentioned.

3.3.5 Multi-modal interfaces

Due to the increased technical skills required to install all sensor devices and setup the multi-modal interfaces of error-aware gaze-based keyboard and MM-Tetris, it was not possible for the Sheba local experimenters to run the part of the protocol involving the use of multi-modal interfaces.

4 CROSS-COHORTS INTEGRATIVE ANALYSIS

There were some differences in the demographics of the three cohorts that participated in the study. For instance, all the SCI participants were only males while the males/females ratio among the other cohorts was ~50/50. All of the NMD participants had no children as opposed to other cohorts. The PD group's average age was larger than the other cohorts and none of them owned a smartphone. Mostly, these differences seem to arise from the clinical differences between the cohorts, e.g. Parkinson's disease affect older individuals and most of the people with a spinal cord injury are males. However, some differences may be the product of demographic and cultural differences between the two countries that were part of the project.

Regarding the primary outcome total usage time, it is possible to see that some cohorts used the MAMEM platform more than others. Specifically, the NMD participants tended to use it the most, while PD participants used it less and the SCI used it the least. The following figure presents the average usage active hours among the different cohorts.

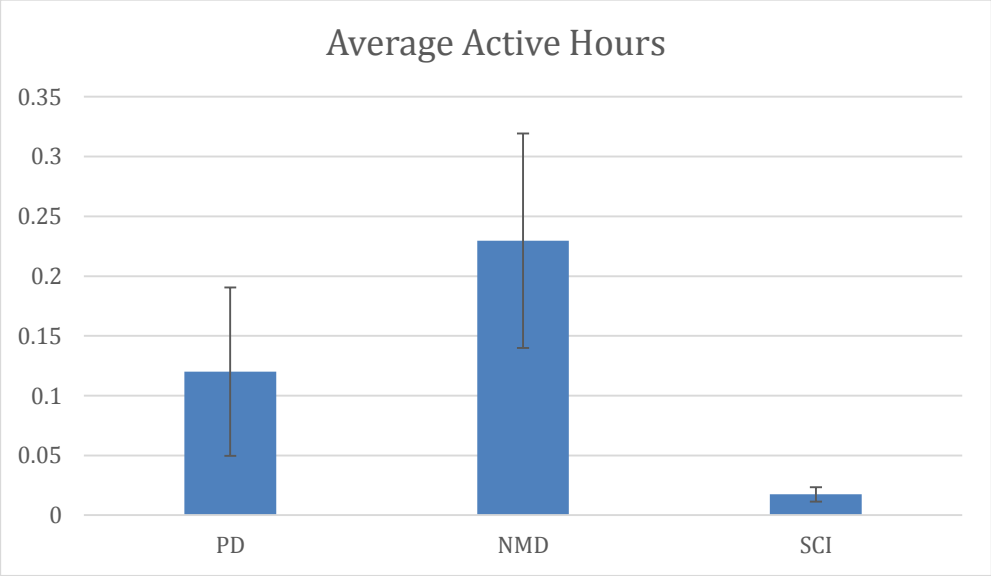

Figure 8 - Average active hours in the three cohorts

This pattern may be the due to clinical reasons, cultural reasons (since PD and NMD participants were from Greece and SCI participants were from Israel), practical reasons (all the SCI participants had a smartphone and reported that they use it the most for all of their internet needs) or perhaps other reasons. A further investigation may be needed to identify the reason of these findings.

Within the cohorts, it is possible to see that there are also considerable differences of usage times among the participants themselves (see participants' usage figures in the results section). These differences were the reason why three users who used the platform the

most were chosen for a more detailed usage analysis. In these cases, as well, individual differences, clinical reasons, or other factors may have been the cause for this usage pattern. In this context, we should mention that in the literature, high levels of new assistive devices abandonment are usually reported (between 30% to 70%, [11-14]) and this high percentage fits the levels of abandonment we see in the current study. Finally, it should be mentioned that due to the high variability of usage time, those who used the platform for longer durations had a large impact on the total average durations of the cohorts, something that could explain the general usage pattern in the three groups.

Regarding social activity of the participants, for a general impression, we calculated the average usage time of the most popular social networks - Facebook and YouTube, across the three clinical cohorts. The following figures presents these usage patterns.

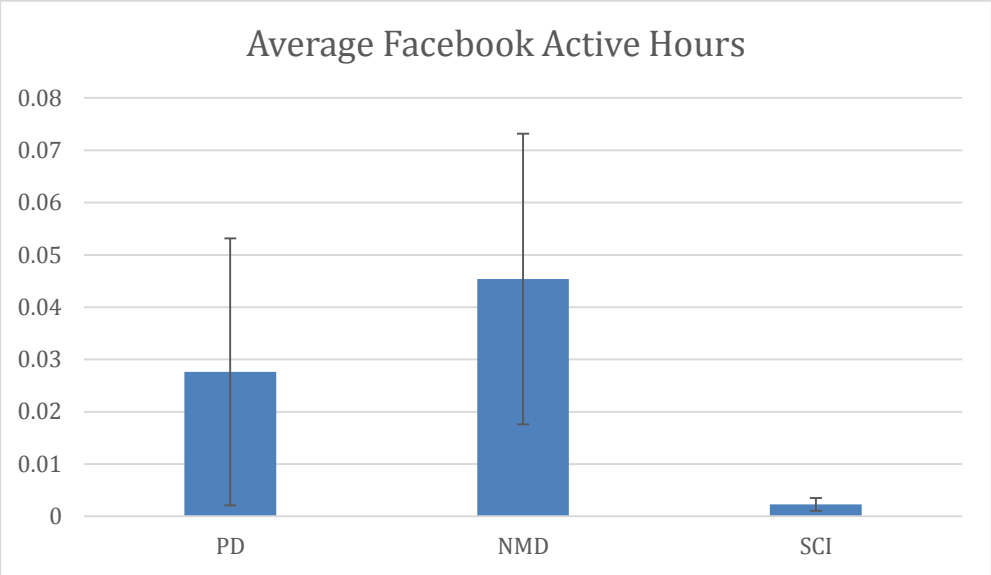

Figure 9 - Average Facebook active hours in the three cohorts

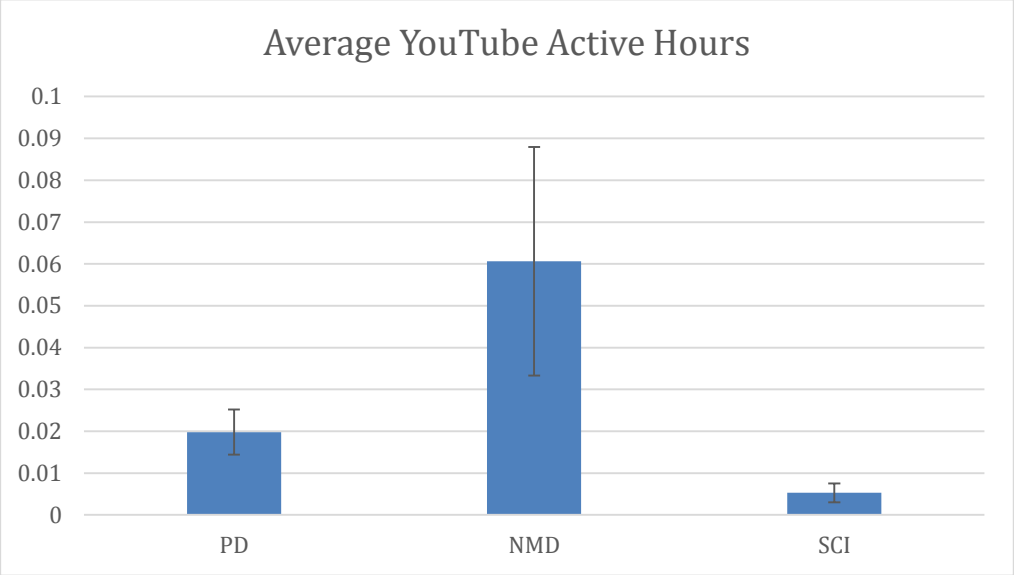

Figure 10 - Average YouTube active hours in the three cohorts

It is noticeable that there are relatively similar differences in the three cohorts but a large difference between the social networks. The differences between the cohorts is probably a direct function of the differences in the general MAMEM usage patterns. The differences between the social networks, however, may be due to the individual differences in usage habits and preferences, which probably enhanced the effect when we isolated three users from each cohort. However, these differences may also be due to the clinical conditions or the social characteristics of the participants, so for instance, these patterns may reflect some participants choosing a more passive internet usage over active usage due to difficulties in typing.

It seems that the most popular websites among the chosen users were search engines sites. This comes as no surprise as most of the MAMEM usage sessions began as this search engine being the homepage.

In regard to the secondary outcomes, when it comes to satisfaction, perceived usability and the evaluation of the persuasive design, all three cohorts reported an above-average score to the interface design of the system measured by the SUS questionnaire and an average-more than average score to the physical attributes of the system measured by the QUEST 2.0 questionnaire. These results were similar across cohorts and generally favourable towards the MAMEM platform. The results of the evaluation of the persuasive design questionnaire in Phase II were relatively similar to the results of the same questionnaire that was passed out in the Phase I of the trials (see D6.4 [4]) and were generally favourable towards the persuasive design elements that were included in the training games.

Concerning the qualitative outcomes, it seems that most of the participants were cooperative and were pleased to participate in the study, as well as help in testing a new assistive device. The testimonials and the experimenter impressions do not seem to show a

clear pattern between the cohorts, however the technical problems reveal that in the SCI cohort there seemed to be more difficulties installing the platform, perhaps due to more restrictions that these participants had. The 2-week phone calls revealed that in all three cohorts, the users were satisfied with the platform, reported it as a bit better than the one that they are currently using and said that they will most likely recommend it to someone else in their condition.

The case study analysis is considered a good tool to understand why a certain person used the system a lot and why another hardly used it. However, an in-depth reading of the analyses of the three users that used the platform the most and those who did not, has not revealed a clear conclusion.

5 GENERAL DISCUSSION

5.1 Summary of findings

The Phase II clinical trials of the MAMEM project were designed to evaluate the MAMEM platform usage among three potential user populations, and to test its potential in enabling socially inclusive usage activities. These clinical trials provided positive indications for MAMEM as an assistive device that enables computer usage and digital social activities, although the usage patterns were highly variable between the different cohorts and participants.

The primary outcomes showed that in some cases, the MAMEM platform was used extensively throughout the one month that the participants had with the platform, and in some cases, it was hardly used. Those who used the system, used it for various needs and activities, among them, participating in social networks that are the targeted activities that promote social inclusion. These results indicate that the MAMEM platform is a feasible and usable tool for promoting social inclusion among those who are socially "left behind" due to physical disabilities. However, the reason why some users chose to use it and some chose not to, is unclear at this stage. It is also worth mentioning here that the abandonment rates of new assistive devices reported in the literature are quite high (up to 60%) and similar to the current rate of abandonment. The reason for this rate is also unknown.

The secondary outcomes of the study provided indications that in general, the MAMEM platform is perceived as a useful, usable and a satisfactory assistive device and the persuasive design elements that were integrated in the training games were generally perceived as favourable. The persuasive design elements that were integrated in the MAMEM dashboard and in GazeTheWeb were not directly assessed in the current study.

The extensive qualitative outcomes that were gathered in the study, in addition to the primary and secondary outcomes, provided a rich data source regarding many aspects of the participants' experiences of using the MAMEM platform. However, these outcomes analysis did not reveal a clear-cut pattern concerning the MAMEM general usage or its use for socially inclusive activities.

5.2 Methodological limitations of the trials and potential future research

Phase II of the clinical trials had some methodological limitations:

- The study was designed as an ecological study and as such there were many variations in the results that originated from its uncontrolled nature. For instance, the number of days with the system varied between cohorts and between participants due to the "messy" lives of the participants and some restrictions of the clinical sites.

- The participants were given the platform to use at their own homes without supervision. Some users used the laptop for reasons other than internet use. Other users moved the system around although they were asked to refrain from doing so and two eye-tracking devices were damaged.
- There were three different cohorts in the study who had three different conditions. Also, the cohorts differed in other demographic and clinical factors that stemmed from their condition. Also, one cohort came from one country and the other two from a different country. These differences have made it harder to understand the pattern of usage results of the MAMEM platform. Especially in light of the outcome measures being computer usage and online social networks participation, which are rather complicated to understand and analyze.

All of the above caused the analyses of the results in the current study to be limited and therefore we suggest that a future investigation is warranted to understand the relations between the usage pattern to demographic, clinical and other factors.

5.3 Recommendation for future use

Recommendation for future use, in light of the results of the Phase II, are hereby suggested:

- Since the results show that not every user found the MAMEM platform as a productive tool to operate computers, surf the web and participate in the social networks, it is recommended for potential users to try the platform for a certain period of time and to assess whether they find it suitable for their needs.
- In light of the difficulties in operating the eye tracker by some of the potential users, a short pre-test of the ability to operate it, is recommended for each potential user before the installation of the platform, in order to see if they are able to do so beforehand.
- Despite difficulties that may arise, it is imperative to locate and set an appropriate operation station, one that will allow operation at the correct height, angle and that will accommodate for the needs of the user such as sufficient room for a wheelchair.
- Most of the participants have some existing means of interaction (e.g., mouse/switch), which highly influenced their acceptance of a novel eye tracking technology. It would be imperative how MAMEM platform could combine eye gaze interaction with mouse, touch, switch and other means of input for better performance and accuracy.
- Finally, the potential users must be explained that the MAMEM platform was designed to facilitate certain computer use aspects that involve surfing the internet and social networks participation and clarify exactly what the MAMEM platform is able to do and what in cannot at this stage. This should be done in order for the users

to adjust their expectations from the platform and to avoid potential disappointments.

6 CONCLUTIONS

Phase II of the clinical trials in the MAMEM project was designed to evaluate its use among the potential user populations. It was conducted in uncontrolled environments, without the presence of experimenters where the novelty of the technology and the persuasive designed elements that were included in the design were the only motivators driving the participants to use the platform.

Phase II successfully met its objective in that it enabled potential users sufficient time to test the system and its primary and secondary outcomes were defined in such a way that they enabled to assess the usage of the MAMEM technology.

These trials provided evidence that the MAMEM platform can indeed serve as an assistive device for some disabled people. However, the usage patterns varied due to various subjective measures of user impairment stage, preferences, prior interaction experience, performance and accuracy. We highlighted some of these measures as part of trial outcome in quantitative and qualitative analysis. In Section 5.3 we provided a few recommendations for future use.

The results of phase II point to some positives indications that the MAMEM platform can provide substantial added value to those who need it. Several participants indicated, and demonstrated, that they could do various sophisticated Web activities that they could not do before. The participant MDA5 is an excellent example for this. Other participants indicated that if their condition will worsen, they believe that they would use the platform more extensively. In this context, it is worthwhile mentioning that MAMEM has "competition", i.e., other aiding devices for computer use. In fact, most of the users who rarely used the platform indicated that they could already use computers by some control of a mouse, or by another assistive technology that they have gotten used to and became comfortable with.

Further, it should also be mentioned that in MAMEM project we worked on the advancement of interaction techniques and application usage, however most discussed limitations of the trials were actually dependent on the hardware technology, e.g., eye trackers functionality and usability like ambient lighting condition, calibration, restart requirement. Several eye tracking manufacturers like Tobii, Oculus are continuously working on improving these aspects, and we envision that the evolution of the eye-tracking technology with MAMEM interaction solutions would certainly resolve many issues. Another consideration is the general shift in the use of digital media from computers to the mobile technology, in particular for social participation and communication. Some of our participants indicated that they hardly use computers and use smartphones instead. Hence the evolution of precise gaze tracking for mobile devices would enhance MAMEM user group satisfaction in future.

The MAMEM platform joins the family of assistive devices for computer use that already exist in the market. Its greatest benefit is that it offers a unique way to 'surf the web' and to participate in online social networks, using eye gaze, and thus offers a solution for those who are unable to do so with their hands due to disabilities. The results of the trials demonstrate that those who find the MAMEM platform beneficial for their needs, tend to use it extensively and for social participation. This way, the MAMEM platform fulfils its purpose to enable disabled people who find themselves in the margins of society, to re-join by means of participation in social interaction.

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A Appendix

A.1. Phase II CRF

MAMEM

CASE REPORT FORM

FEASIBILITY AND USABILITY OF A NOVEL ASSISTIVE DEVICE FOR COMPUTER USE

PHASE II

General instructions for completing this Case Report Form (CRF)

- Use only black ink. Other colors will not copy correctly
- The principal or co-investigator must sign and date the reports, certifying the accuracy and completeness of the data
- All pages must be filled out. If a question does not apply, write NA; if a test is not done, write ND; if the result is 0, enter 0.

- Do not use whiteout. If an error is made, draw a single line through the error, write the correct entry in the adjacent space.

Participant Screening

To be filled by the Investigator or co-Investigator

INCLUSION CRITERIA for SCI participants

Men and women aged 18-80	❑ yes	❑ no, exclude participant
Suffering from a complete or incomplete spinal cord injury from C5 and above	❑ yes	❑ no, exclude participant

INCLUSION CRITERIA for PD participants

Men and women aged 50-80	❑ yes	❑ no, exclude participant
Suffering from PD at stages 3-4 (Hoehn & Yahr scale) or stage 2 but with severe disability in upper limbs	❑ yes	❑ no, exclude participant

INCLUSION CRITERIA for NMD participants

Men and women aged 18-80	❑ yes	❑ no, exclude participant
Suffering from any neuromuscular disease	❑ yes	❑ no, exclude participant

EXCLUSION CRITERIA

Involuntary eye movements	❑ yes, exclude participant	❑ no
Implanted devices that may interfere with the brain electrical activity recorded by the EEG sensor	❑ yes, exclude participant	❑ no
Medical conditions that may induce seizures	❑ yes, exclude participant	❑ no
Brain conditions such as brain trauma, brain surgery, stroke that may interfere with the brain electrical activity recorded by the EEG sensor	❑ yes, exclude participant	❑ no
Any psychiatric (e.g., major depression) or cognitive conditions that may interfere with understanding the instructions or with participant cooperation	❑ yes, exclude participant	❑ no
Drugs or alcohol abuse	❑ yes, exclude participant	❑ no

Inability to operate the eye-tracker (I.e. wearing very thick glasses)	❑ yes, exclude participant	❑ no

THE PARTICIPANT IS SUITABLE FOR THE STUDY:	❑ yes	❑ no, exclude participant
Remarks:		

Investigator/co-Investigator name:
Written informed consent obtained: ❑ yes ❑ no, exclude participant *(Sign the inform consent and give a copy to the Participant)*

Overview of the “Before”, “During” and "After" Steps

Install monitoring mechanisms one month in advance of MAMEM usage onset	This is especially important for Social Tracker This will ensure that we have enough “before” and “after” data
Perform the demographic and clinical questionnaires	Can be done over the phone, anytime before the 1st day.
Prepare materials for first interview	1. List of recommended sites to visit 2. List of contact details in case they need help with system operation 3. Card set 4. “Manual” / “How to”
Perform the parts of the “Before” interview	1. Explain MAMEM study 2. Carry out the social inclusion part of the questionnaire 3. Training 4. Carry out the training evaluation questionnaire 5. Encourage social activity and make recommendations 6. Explain audio diaries 7. Ensure person understands troubleshooting steps, provide contact details if they get stuck 8. Explain what comes next
Perform the 2-week usage milestone	1. Telephone call at 2 weeks of usage 2. Evaluate person’s comfort level with MAMEM 3. Check for problems and issues 4. Check how MAMEM compares to their previous device 5. Check whether user is engaging in social activities the same, more or less versus their previous device
Perform the parts of the “After” interview	1. Carry out the social inclusion part of the questionnaire 2. Carry out the QUEST 2.0 and SUS questionnaires

Install monitoring mechanisms

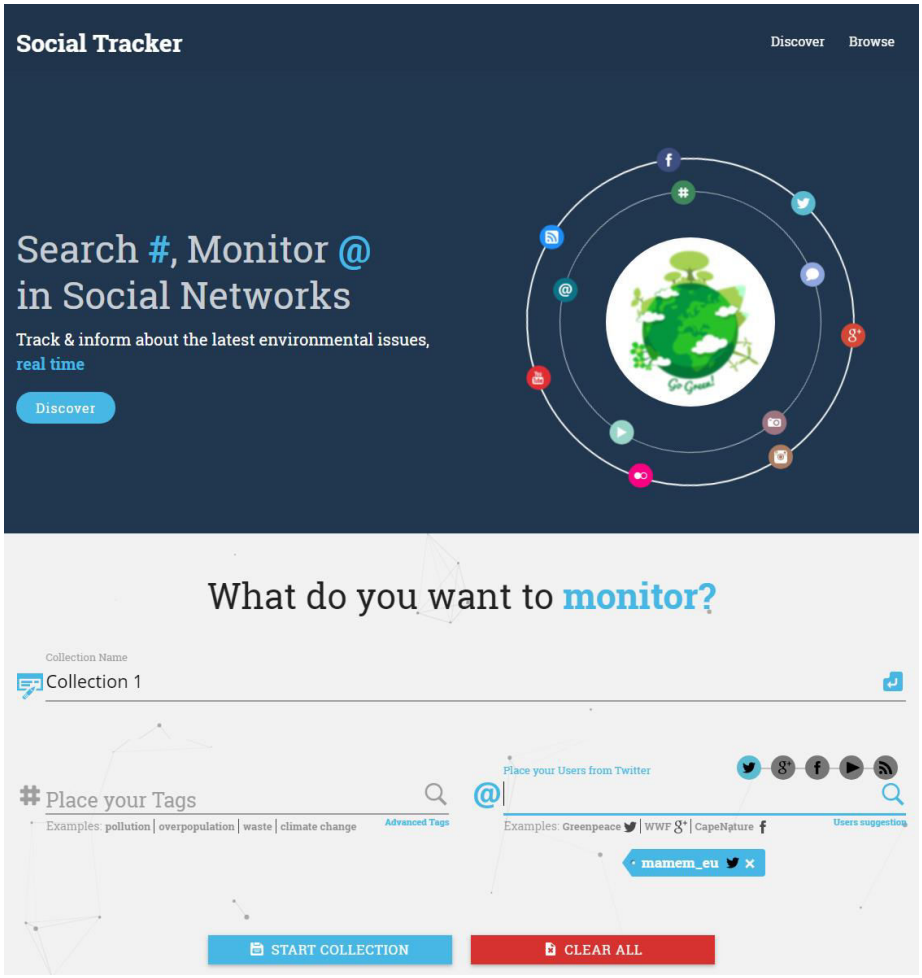
This part can be done over the phone. First of all, check if the user has or wants to create and use **Twitter** or **Google Plus** accounts. If he/she doesn't you can skip the Social Tracker step.

Social Tracker - Setup Instructions

Instructions available also online:

https://docs.google.com/document/d/1xSK6VuiWO5jH-_38G1ALOVjA_vc0HemN4Z46W4w_w48/edit?usp=sharing

1. Create & write down a user id, based on the name of the patient. Try to write at least 8 characters with numbers to avoid overlapping users. (eg: '**tasos_pap45**').
2. Open a browser and visit the following url, after substituting the user id (**tasos_pap45**) with the one you created in step 1:
   http://augreal.mklab.iti.gr:81/ui/index.html?user_id=**tasos_pap45**
3. Fill-in the Collection Name field with any name you desire (for example **collection1**), leave the **Place your Tags** field empty and add the social media accounts of the user by:
   Clicking first the **Twitter** or **Google Plus** icon and then fill in its respective username or handle. There is an auto-complete feature, that shows you a list with the users that the service have found, so as to be sure that this is the correct user you want to add. (Facebook and YouTube is unsupported at this point so don't add them).
4. If you have done everything according to the three steps you should see something similar to the picture below:



5. Click on the **Start Collection** button to start the collection service.

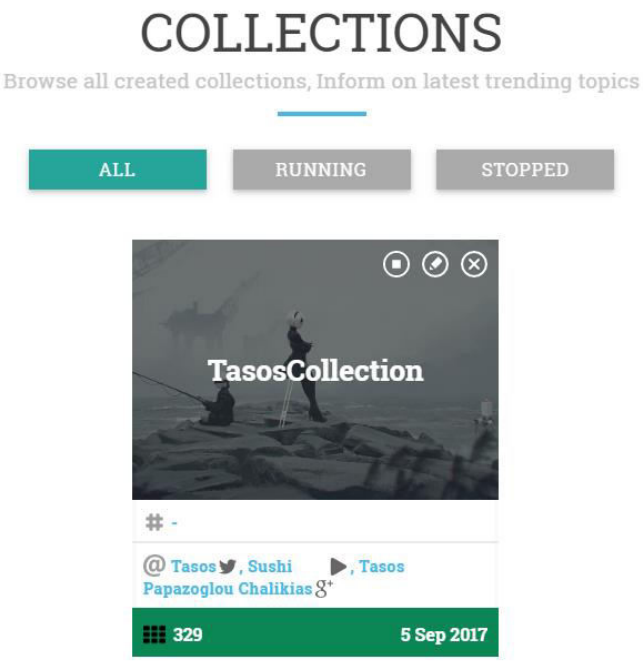
You can create more than one collections, but it's best if you just leave it at one!

You can also edit your collection by clicking on the small edit (pencil) button to the top right of the collection card (as shown in the picture below). While editing you can add or delete the usernames or handles of the social networks you have set up.

Don't forget to write down the user id you created in step 1, for each participant!

User id that was created (if relevant) : _____

After having all user ids, send them to me so I can check that everything runs smoothly!


COLLECTIONS
Browse all created collections, Inform on latest trending topics
ALL
RUNNING
STOPPED
TasosCollection
#
@ Tasos , Sushi , Tasos Papazoglou Chalikias
329
5 Sep 2017

Telephone demographic and clinical questionnaires

This part of the questionnaire can be carried out via a telephone interview and is directed at new participants only. This information will already be available in the case of participants who have been already involved in previous steps of the study

Date performed: _____

DEMOGRAPHIC DATA

Age	
Gender	Male / Female
Marital status	Single / married / Divorced / widower/ lives with a partner
Number of children	
Ages of children	
Educational years	
Occupation	
If employed/working	Full time / partial
Hours employed/working per week	
Hand-use	Left-handed / Right-handed

CLINICAL DATA (for SCI participants)

Diagnosis: (Neurological level of injury (NLI) & American Spinal Cord Injuryassociation – (ASIA) impairment scale (AIS)	_____

Reason of SCI	Traumatic: ☐ Sport ☐ Assault ☐ Transport ☐ Fall ☐ Other: _____ Non-traumatic: _____
Years with SCI/year of injury	
What type of chair do you use for transport?	Motorized/regular
Do you move yourself?	Yes /no
Do you have a car?	Yes / no
If yes, Do you drive?	Yes / no
How many hours per day (approximately) do you spend in bed?	_____
For how long have you been in a rehabilitation ward / day care ward, if any?	_____ _____
Please specify from where you get the financial support (e.g. medical insurance) that you are provided with, in order to address your disease).	_____

In which of the following parts of the body do you present partial or complete bradykinesia/numbness?

	Tongue	Jaw	Neck	Shoulders	Arms	Elbows	Wrists	Fingers
Complete								
Incomplete								

CLINICAL DATA (for PD participants)

1. Age at diagnosis _____
2. Disease duration: _____

3. H&Y scale _____
   (Instructions to interviewer: if needed, consult with MD/medical records)

4. Are you in a wheelchair? Yes / No

5. Are you in bedridden? Yes / No

6. Have you been in a Vocational rehabilitation Center or program? Yes \ no

7. If so, please specify what center/program and for how long:
   _____

8. Please specify the financial support (e.g. Medical insurance) you are provided with, in order to address your disease).
   (Instructions to interviewer: only name the major sources of income)
   _____

9. In which of the following parts of the body do you present partial or complete immobility?

	Tongue	Jaw	Neck	Shoulders	Arms	Elbows	Wrists	Hands	Fingers
Complete									
Incomplete									

10. In which of the following parts of your body do you have tremor?

	Tongue	Jaw	Neck	Shoulders	Arms	Elbows	Wrists	Hands	Fingers
Severe									
Mild/moderate									

11. In which of the following parts of your body do you have dyskinesias (*involuntary movements due to medications)*

	Tongue	Jaw	Neck	Shoulders	Arms	Elbows	Wrists	Hands	Fingers
Severe									
Mild/moderate									

CLINICAL DATA (for NMD participants)

1. Diagnosis(*which kind of NMD your diagnosis is related to*): _____

(Instructions to interviewer: if needed, consult with MD/medical records)

1. Years since first diagnosis: _____
2. Have you had any spinal surgery because of your disease? Yes / No
3. Are you in a wheelchair? Yes / No
4. Are you in bedridden? Yes / No
5. Have you been in a Vocational Rehabilitation Center or program? Yes \ No
6. If so, please specify what center/program and for how long:

_____

7. Please specify the financial support (e.g. Medical insurance) you are provided with, in order to address your disease).
   (Instructions to interviewer: only name the major sources of income)
   _____
8. In which of the following parts of the body do you present partial or complete immobility?

	Tongue	Jaw	Neck	Shoulders	Arms	Elbows	Wrists	Hands	Fingers
Complete									
Incomplete									

Computer use habits

1. How is your social life affected by your disability?
   - ☐ My social life is normal.
   - ☐ There is no significant effect on my social life apart from limiting energetic aspects, such as dancing.
   - ☐ My social life is restricted and I do not go out as often.
   - ☐ My social life is restricted to my home.
   - ☐ I have no social life and feel lonely.
2. Have you any kind of hobby or recreational activity?Yes /No
3. If yes, please specify: _____
4. How is your mobility outdoors affected by your disability?
   - ☐ I travel frequently for needs / pleasure.
   - ☐ I travel sometimes.
   - ☐ I travel very rarely and only when there is an absolute need.

☐ I cannot travel and must stay home.

5. Of the following systems, which do you own?
   ☐ Desktop computer
   ☐ Laptop computer
   ☐ Tablet
   ☐ Smartphone

6. If you own more than one, which one do you use the most?
   _____

7. Do you use a PC? Yes / No
   (Instructions to interviewer: if the subject does not use a PC – even if he/she owns one - go straight to chapter III.)

8. If so, how many hours (approximately) a day do you use it?
   _____

9. How many years of experience do you have using a computer?
   _____

10. Please indicate your main uses of your computer system and the three most important ones:
    (*Instructions to interviewer: can choose more than one; mark an x next to the important three uses*)

☐ Social participation (Facebook, forums, etc.)	
☐ Productive activities (writing, editing, etc.)	
☐ Study (on-line courses, articles, etc.)	
☐ Games	
☐ Recreation (movies, music, crossword puzzles, blogs, etc.)	
☐ Communication (email, Skype, etc.)	
☐ Activities of daily living (purchases, payments, bank, etc.)	
☐ Information (Wikipedia, governmental sites, news, maps, etc.)	
☐ Other: _____ _____	

11. Please indicate the main applications you use and the three most important ones:

(Instructions to interviewer: can choose more than one; if chosen, name the main application the subject use; mark an x next to the important three)

☐ Internet browser: _____	
☐ Email client:_____	
☐ Word processor:_____	
☐ Audio/video/image applications:_____	
☐ Spreadsheets (e.g. excel):_____	
☐ Computer games:_____	
☐ Presentation software:_____	
☐ Programming/database:_____	
☐ Media editing applications:_____	
☐ Other: _____ _____	

12. Which operating systems do you work with?
    - ☐ Microsoft Windows
    - ☐ Unix / Linux
    - ☐ Apple MacOS

13. To what extent do your physical symptoms impair your ability to use the computer as extensively and as widely as you might like?
    - ☐ My symptoms do not interfere at all with my ability to use the computer
    - ☐ My symptoms interfere a slightly
    - ☐ My symptoms interfere fairly much
    - ☐ My symptoms interfere very much
    - ☐ I am not sure/I do not know

The “BEFORE” interview

The guidelines for the person who will conduct the questionnaire interview are outlined below:

a. Introduce yourself fully, explain the scope of the MAMEM project and of the interview.
b. In conducting the interview with the person with the disability, be sensitive to signs of fatigue, and to whether fatigue causes them to mechanically go through the answers without thinking them through. In that case, it is best to stop and continue the interview at another time.
c. Go through trouble shooting options: explain who and how can be contacted if participants get stuck, or have problems using MAMEM
d. Encourage social activity: provide the recommended list of sites, encourage them to use them
e. Explain audio diaries. Explain the mechanics of how they can use the media player already in their laptop to record their voice. Explain that they are invited to provide at least 3 entries
f. Describe what comes next: that there will be follow up calls checking on their experience

Explain the objective of the study

It is important for the respondents in this study to fully understand the scope and significance of the MAMEM project, and the social inclusion study. We propose, here, a way to present the MAMEM scope:

"The objective of this study is to fully understand if and how your use of MAMEM may influence your quality of life, and sense of independence, in terms of social life, hobbies, recreation, information, education and opportunities for employment. Your participation in this study is instrumental in developing a specialized technology like MAMEM, which will assist people with difficulties to use the computer and the Internet with their eyes and mind.

This questionnaire will first ask a few questions about your digital habits and life, and then will probe your opinion of MAMEM, given the few hours of exposure you have had to it. After using it for a month, you will be asked these questions again, in order to see whether and how MAMEM has made it easier and better for you to interact online, and to seek opportunities, resources and information that is important to you.

When considering your answers please take into account your regular every day activities. Every one of your opinions is very valuable for this research. So, we will go through the questions one by one, carefully. Should you at any point, need a break, feel free to take it. Your comfort is the priority here. This process is expected to take up about 45 minutes of your time, or less."

Social inclusion

Instructions to interviewer: use a card for each of the questions Q1, Q2, Q3, Q4, Q5. *The card presents the matrix of responses. Give the card to the interviewee while you are reading each statement. The person can read the answers, while you are asking a series of multiple statements and the answers will not need to be repeated for each statement. This will speed up the interview time. Examples of cards with answers for Questions 2 and 3 follow below:*

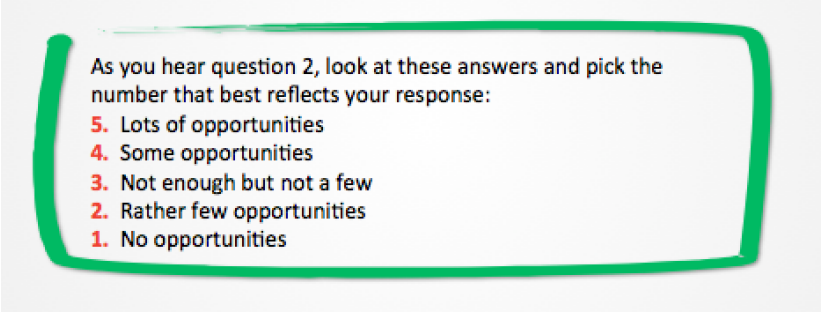


Figure 1: Example of a response card for Question 2

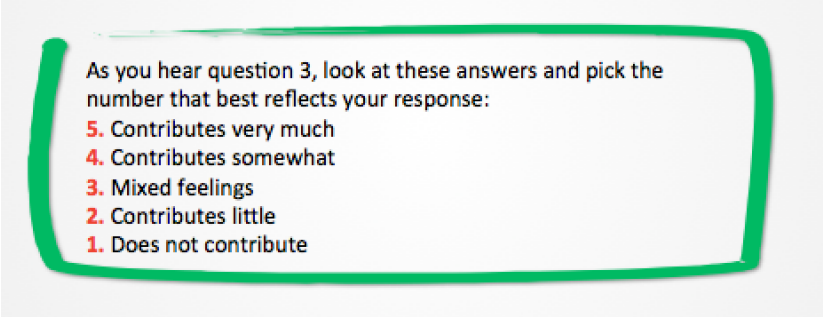


Figure 2: Example of a response card for Question 3

Q1. I will read you some statements that reflect someone's feelings about life, and I would like you to rate how true they are for you on a scale of 5 to 1, where 5 means the statement is totally true for you and 1 means that they statement is not at all true for you

	Very true for me 5	Somewhat true 4	Mixed feelings 3	Not that true for me 2	Not at all true for me 1
Given my disability, I feel included in most aspects of life around me					
I feel more or less optimistic about the future					

I feel I am playing a useful part in society					
I feel that who I am and what I do is valued by others					

Q2. I will read you some digital activities and I would like you to tell me how much each of them contributes to your feelings of inclusion in society and ability to make the most of resources available for your benefit. Please on a scale of 5 to 1, where 5 means that digital activities are totally contributing to your feeling of inclusion and 1 means that they are not contributing at all:

	Contributes very much 5	Contributes somewhat 4	Mixed feelings 3	Contributes little 2	Does not contribute 1
Active use of digital technologies overall					
Active participation in social media like Facebook, Twitter, Instagram					
Active participation in business, education sites like Linked In, Quora, Academia, etc.					
Attending online courses					
Engaging in online job hunting					
Participating in groups, for a, relevant to your interests and needs (health or otherwise)					
Playing online games with others					
Watching /reading content (videos, movies, books, articles)					
Using specialized software and apps relevant to your hobbies (e.g. photoshop, Picasa, etc.)					
Using digital technologies to earn income					
Hiring help online and finding support on issues that concern you					

Q3. I will read you some statements now regarding your digital activities and I would like you to rate how true they are for you on a scale of 5 to 1, where 5 means the statement is totally true for you and 1 means not at all true for you

	Very true for me 5	Somewhat true 4	Mixed feelings 3	Not that true for me 2	Not at all true for me 1
There are people online that I trust to support or help me with my problems					
When I go online, there are people I can turn to for advice, about issues or decisions I have to make					
When I feel lonely there are people online that I can connect with					
I engage often enough in digital/online activities that fascinate and entertain me					
My interactions with people online make me want to try new things					
My online activities make me feel a part of a larger community					
I have opportunities to be active and creative through digital / online activities					
My digital/online activities give me a sense of freedom and choice					

Q4. I will read you some statements now regarding the amount of opportunities you feel you have access to, by engaging in digital and online activities. Please rate the statements from 5 to 1, where 5 means you feel you have access to a lot of opportunities and 1 means there are no opportunities.

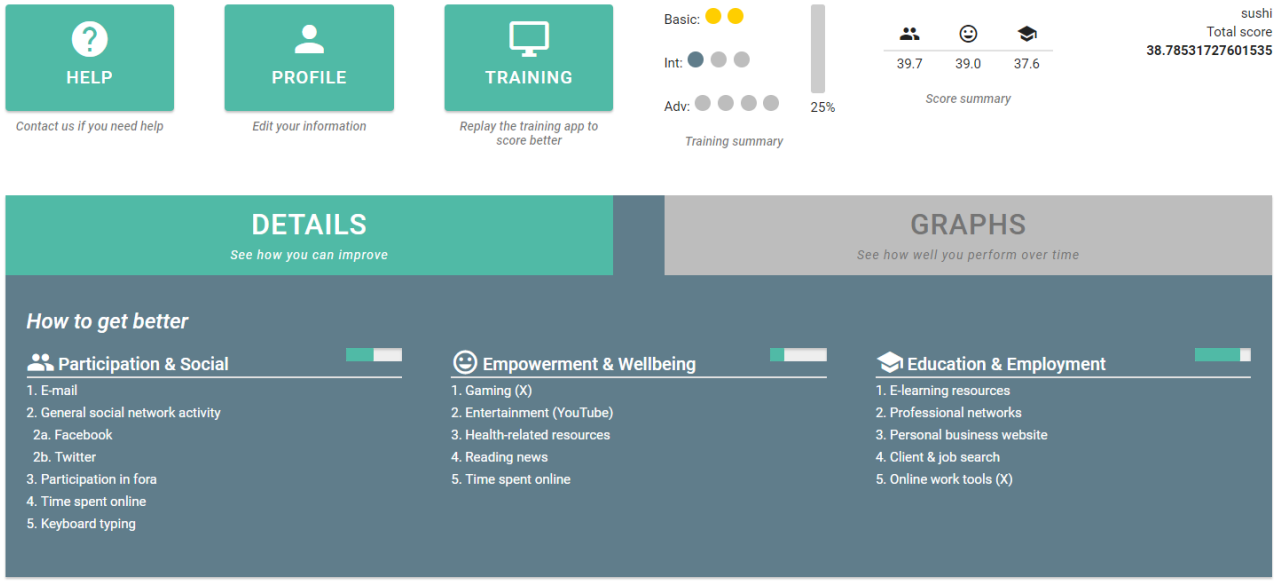
	Lots of opportunities 5	Some opportunities 4	Not enough but not a few opportunities 3	Rather few opportunities 2	No opportunities really 1
I feel I have access to opportunities to find employment					
I feel I have access to opportunities to acquire new skills					
I feel I have access to opportunities to					

develop business ideas					
I feel I can pursue promising business contacts					
I feel I can learn more about health issues					
I feel I can communicate and flirt with members of the opposite sex					
I have opportunities to advance my hobbies and my creativity					
I have the opportunity to be a volunteer and to support others meaningfully					

Setting up a user account – Information about the Homepage

1. **Set up Facebook Monitoring mechanism:** First of all, the experimenter must send his Facebook account to me (Tasos Papazoglou-Chalikias of CERTH) so I can add him as a MAMEM Facebook App admin. Then the experimenter should head to https://developers.facebook.com/ access '**My Apps**' at the top right of the page and open the **MAMEM Statistics** app. In there, click on the **Roles** section form the left sidebar. Click on the '**Add Testers**' button and write the full name or username of the participant, and hit **Submit**. Now the participants Facebook data are ready for the crawling process.
2. **Register participant**: Visit http://augreal.mklab.iti.gr/mamem/gtw-home/register.html from a normal browser and add all information needed for the patient. **Remember to save somewhere the E-mail and Password provided**! In the **Social Tracker** field put the **user_id** that you created when setting up the **Social Tracker** account.
3. **InstallGaze The Web:** Launch the installation wizard and provide the E-mail and Password when prompted, which were saved in step 1.
4. **Homepage**: **T**he MAMEM Dashboard is set as the Homepage, which GTW always opens when started. If the participant has a Facebook account, he should always click on **Continue with Facebook**. If there is no Facebook account, then always click on **Continue without Facebook** button. The Homepage acts like a central hub for the participant. Please explain to the participant the following information about the Homepage:

   On the Homepage (See the Picture below), the participant will find three important buttons:
   - Help: Contact someone from the MAMEM project if they need help on using the platform
   - Profile: Edit their information by clicking on the **Profile** button,
   - Training: Initiate the training tasks by clicking on the **Training** button
     i. You can use the training button as often as you like to go to the training tasks again and learn better how to use the MAMEM system.
     ii. Right next to the training button, the participant can see a brief overview of his or her training progression.

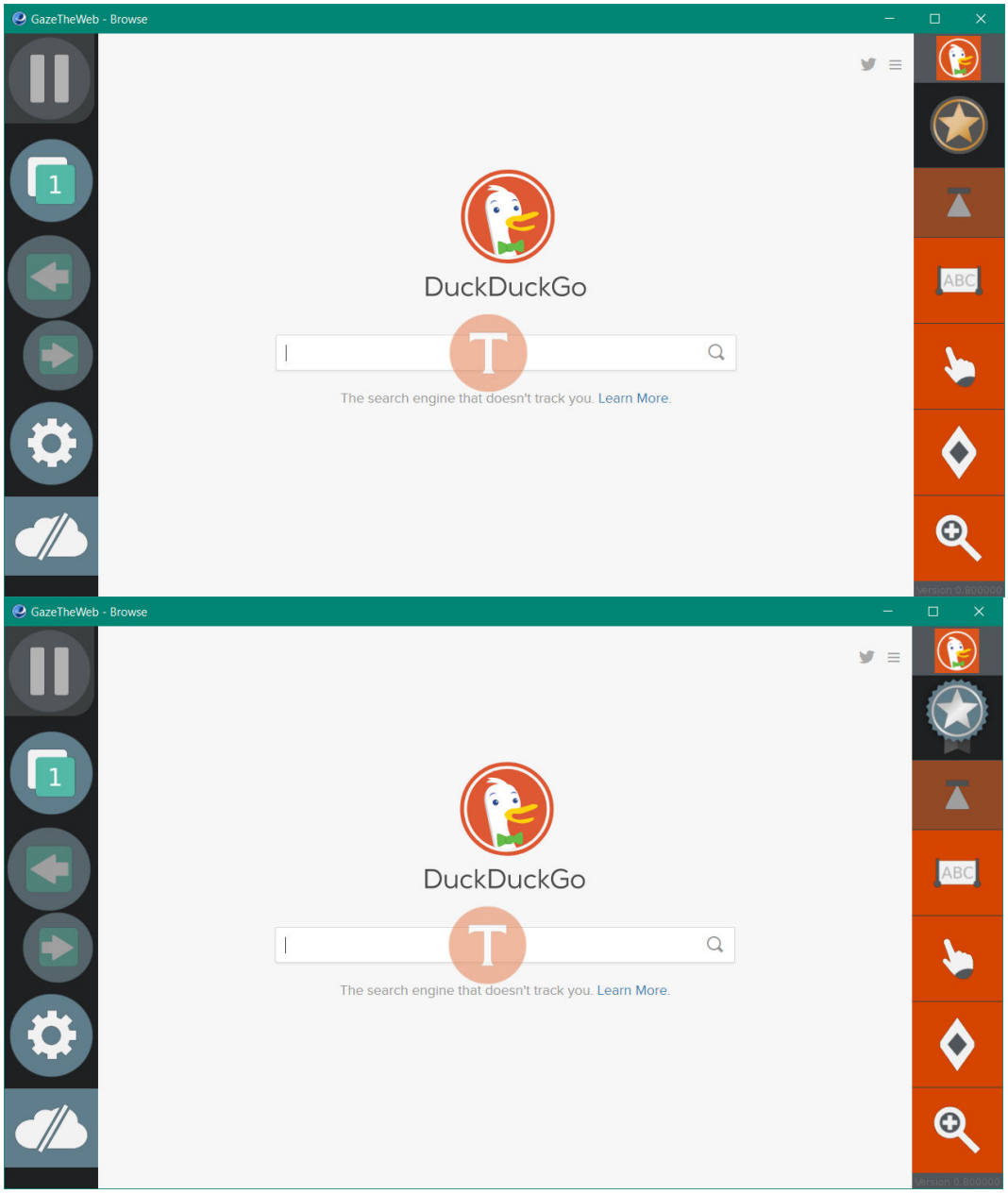


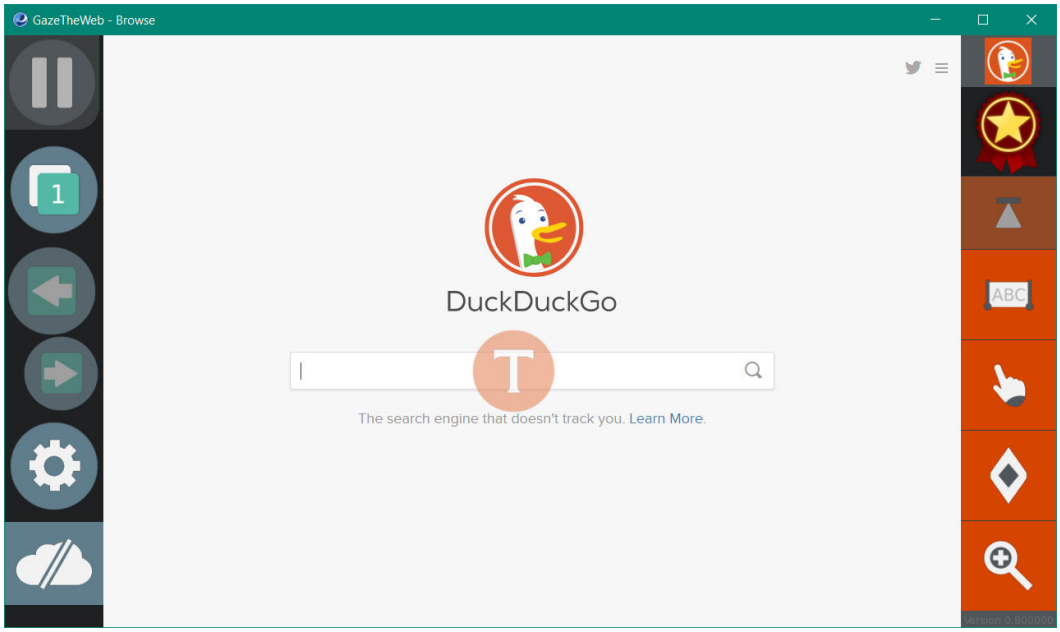
Importantly, also on the Homepage, the participant is provided with feedback about his or her digital social inclusion behavior. As explained before, there are three domains in which you can perform this kind of behavior:

- Participation and social: e.g., send an email
- Empowerment and wellbeing: e.g., Gaming / play online games
- Education and employment: e.g., do E-learning.

While browsing, the MAMEM system informs the participant about his progress, that is, in how far the user uses the MAMEM system for digital social inclusion behavior: In the top right-hand side of the GazeTheWeb browser, a medal is displayed (see Figures below):

- Bronze MAMEM medal: You could use MAMEM for more social inclusion activities. Check out the Homepage feedback for specific feedback and advice.
- Silver MAMEM medal: You use MAMEM for social inclusion activities, but can still do so more. Check out the Homepage feedback for specific feedback and advice
- Gold MAMEM medal: You use MAMEM for a lot of social inclusion activities! Check out the Homepage feedback for specific feedback and advice.

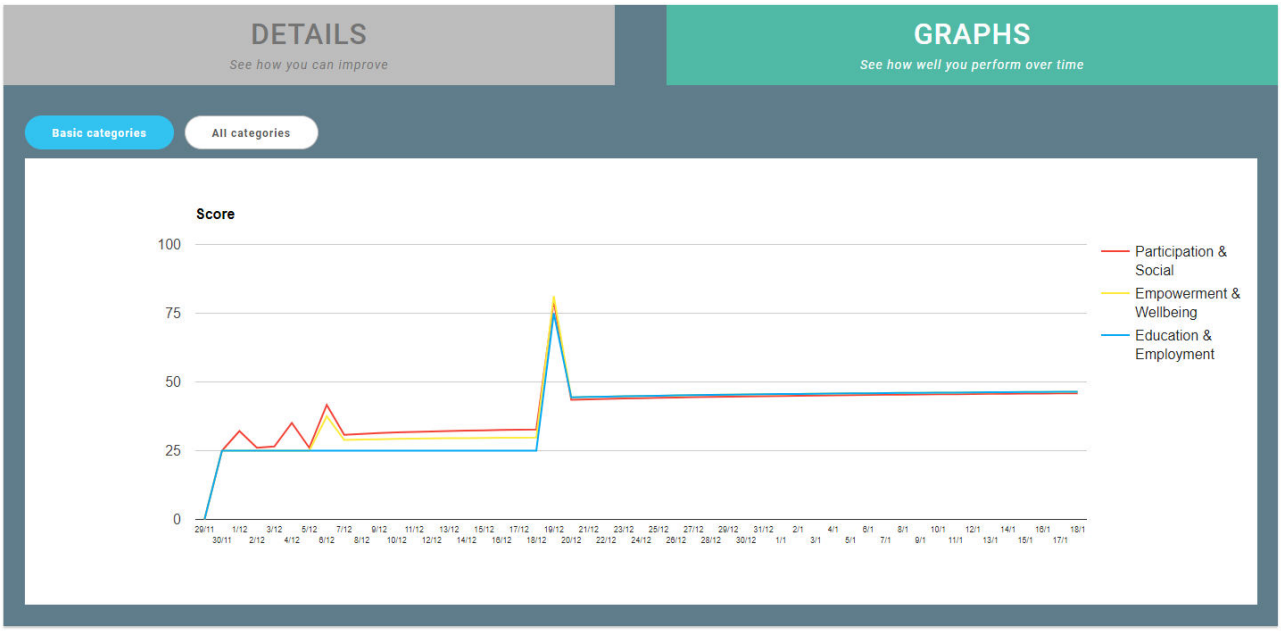

GazeTheWeb - Browse
DuckDuckGo
The search engine that doesn't track you. Learn More.
GazeTheWeb - Browse
DuckDuckGo
The search engine that doesn't track you. Learn More.



On the Homepage itself, participants can find a **score summary** for the three domains of social inclusion, and a **total score**.

Also, there is more detailed information on two tab-pages:

- DETAILS
  - On the Details page, the participant can learn what his or her scores are on the three domains and on the various specific activities for each domain.
  - For example, a participant might still improve his or her score on 'E-mail'
  - Under the question mark, the participant can find more information for increasing that score. That is, under the question mark, links to websites are provided for each specific activity.
- GRAPHS
  - On the Graphs page, the participant can see a chart showing their progress over the days of the experiment for the three domains of social inclusion behavior.
  - For an example, see Picture Y below:



Please remind the participant that MAMEM is mainly for social inclusion activities (e.g., sending email, reading the news, or e-learning). The MAMEM Homepage will help them use MAMEM for this. The MAMEM Homepage will show them how good they are using MAMEM for what it was intended for!

Training

Before training part

- The login process of the user is performed automatically, when clicking on the '**Training**' button from inside the Dashboard.
- Make sure that the URLs for **www.youtube.com**,**www.twitter.com** and **www.picresize.com** are bookmarked in the GTW browser.

Instruction for the experimenter:

The training part has been gamified according to the persuasive principles. This practically means that the training is in a form of the game which leads the user to the different tasks and finally to its completion. However, the experimenter must intervene when he/she considers that it is necessary (i.e., user cannot proceed with a task and is already frustrated).

Overall, the training has three different levels: basic, intermediate and advanced. Each level consists of a specific set of tasks: 2 for the basic, 3 for the intermediate and 4 for the advanced levels. Experimenter should focus on the following:

- The table below provides an overview of the three levels and their set of tasks as well as the performance measurements and it must be filled accordingly.
- The experimenter needs to control the experiments based on his/her impressions. In case of failure in performing training tasks, after 1.5h of futile attempts and insufficient progress, the training must be terminated.

Detailed procedure

- No need to login or create credentials this time. Login is performed automatically.
- Open the GTW Browser. The Homepage is loaded automatically. Click on the **Continue with Facebook**or **Continue without Facebook** button, accordingly.
- Wait for the homepage to load and then click on the **TRAINING** green square button.

- The training is now initiated.

Training tasks analysis sheet:

	Level	Number of repetitions	Number of success	Best task time in seconds (if available)
Basic tasks	focus on several locations			
	focus long enough on sequence of locations			
Intermediate tasks	use of scrolling, finger-point button and go backward			
	zooming and keyboard typing (BUG: clicking does not work when zoomed in learning app)			
	select, copy and paste			
Advanced tasks	gaze visualization toggling			
	input URL and abort			
	use the word prediction			
	bookmark			

Persuasive training questionnaire

This questionnaire pertains to the first part of the training and consists of 18 questions. Most of these questions present a statement (e.g., “I like strawberries”) after which you can indicate whether you agree with that statement or not, by encircling (with a pen or pencil) the number that corresponds to your answer.

		Strongly disagree	Moderately disagree	Somewhat disagree	Neutral (neither agree nor disagree)	Somewhat agree	Moderately agree	Strongly agree
1	The MAMEM system did not scare me at all	1	2	3	4	5	6	7
2	Operating the MAMEM system made me nervous	1	2	3	4	5	6	7
3	The MAMEM system made me feel uncomfortable	1	2	3	4	5	6	7
4	The MAMEM system made me feel uneasy	1	2	3	4	5	6	7

The next question is a bit different. Please indicate a number between 1 and 10 to indicate how confident you are that …

			Not at all confident			Moderately confident				Totally confident		
5	I could complete the training tasks using the MAMEM system…	…if there was no one around to tell me what to do.	1	2	3	4	5	6	7	8	9	10
		…if I had just the build-in practice games for	1	2	3	4	5	6	7	8	9	10

		practicing										
		…if someone showed me how to do it first.	1	2	3	4	5	6	7	8	9	10

The next questions again present a statement, and you can indicate your agreement or disagreement.

		Strongly disagree	Moderately disagree	Somewhat disagree	Neutral (neither agree nor disagree)	Somewhat agree	Moderately agree	Strongly agree
6	I had control over using the MAMEM system	1	2	3	4	5	6	7
7	I have the skills and knowledge necessary to use the MAMEM system	1	2	3	4	5	6	7
8	Given the skills and knowledge it takes to use the MAMEM system, it was easy for me to use the MAMEM system	1	2	3	4	5	6	7
9	My interaction with the MAMEM system was clear and understandable	1	2	3	4	5	6	7
10	I find the MAMEM system to be easy to use	1	2	3	4	5	6	7

11	I find it was easy to get the MAMEM system to do what I want it to do	1	2	3	4	5	6	7
12	I find using the MAMEM system enjoyable	1	2	3	4	5	6	7
13	The actual process of using the MAMEM system was pleasant	1	2	3	4	5	6	7
14	I had fun using the MAMEM system	1	2	3	4	5	6	7
15	The training tasks motivated me to train my MAMEM skills (e.g., focus with my eyes, scroll the screen down, etc)	1	2	3	4	5	6	7
16	The games in the training tasks (e.g., collecting points) motivated me to do those tasks	1	2	3	4	5	6	7
17	I had the feeling that the messages of the MAMEM system were intended for me	1	2	3	4	5	6	7
18	Assuming I had access to a MAMEM	1	2	3	4	5	6	7

	system, I intend to use it.							

Thank you for filling out the first part of this questionnaire

Audio diary guidelines for participants

The objective: audio diaries provide to the participants the opportunity to express their reactions to the MAMEM technology, during its usage, without any time lapse and without filtering thoughts and reactions. The participants will be encouraged to voice their feedback, opinions, ideas, spontaneously, as they occur, during the use of MAMEM. The context of the Pre MAMEM interview is ideal to explain the process and the media player software usage that will be required. It is state to the participant the following:

"Your personal view and opinion of how MAMEM works for you is very important and can only partly be captured in a questionnaire. Ideally we would like you to record your opinion, in your own words, on your media player after you have used MAMEM for 6 days, for 10 days, and at the end of the trial period. There is no right or wrong way to do this, just whatever comes to your mind as interesting to note and record. Please try to record your opinion during or right after you have finished a session at the computer using MAMEM. Each recorded opinion may last minutes or more. The questions you may express your opinion on are the following:

- ***Does MAMEM influence at all theway that you interact with people online? Please specify.***
- ***Once you become efficient and comfortable using it, do you believe it might influence the way you seek information, resources, contacts and networks, or not? Please specify.***
- ***If you were to be using MAMEMcontinuously and at the level of familiarity you have with your current device, would it have an impact on your interactions with people and resources or not? Please specify.***
- ***Do you feel that MAMEM may influence your opportunities to connect, to learn, to work, and to have fun online, once you become agile with it, or not? Can you specify?***

There is no right or wrong answer in explaining if and how MAMEM makes (or could make) a difference in your daily life.

Encourage social inclusion and inoculate in relation to comfort levels

“We welcome you to visit the recommended sites. We believe it would be interesting to explore them using MAMEM, and to exhaust the MAMEM potential by doing as much and as widely as possible using it.

Also, keep in mind that up to now you have been using a digital device (laptop, computer) with which you are fully familiar, comfortable and fast. Please keep in mind that you will need some time to become as familiar and comfortable with MAMEM. Please keep this in mind when you evaluate MAMEM’s usage.”

List of recommended sites

The objective: to ensure that at the end of the study the individual has explored more avenues for personal, social, professional growth.

Each cohort needs to prepare a list of sites, which will be recommended to the participants. Some of them he/she will already be familiar with, but others will not be. The list of sites needs to include sites in accordance to digital inclusion indicators: education, social networks, professional sites, and health resource sites.

Be prepared to provide the following instructions:

"Here is a list of recommended sites that we thought you might find useful or interesting. They can also be found through the MAMEM Homepage. We would like you to "play" with each of them, as a way of trying out more things using MAMEM. Thereby, you can increase your scores and win the Bronze, Silver or even Gold MAMEM medal!"

For participants in Israel:

Facebook

YouTube

Walla.com

Ynet.com

coursera.com

sites related to their condition

For participants in Greece:

LinkedIn

Slideshare
Facebook
edX.com
coursera.com
e-lance.com
karriera.gr
skywalker.gr
sites related to their condition

List of contact details

The objective: ideally, we want to be able to show the after MAMEM the person has visited more sites and carried out more online activities related to social inclusion, versus before using MAMEM.

Provide a printed list of names and contact details for:

- Technical help
- Social inclusion help (please direct Greek and English speakers to chariskominatou@mindsearch.gr or Hebrew speakers to amihai.gottlieb@gmail.com for any information on social inclusion activities, for test Facebook Messenger/Facebook voice call interaction, etc.) Please express the following to the participants, regarding social inclusion activities:
  "There will be a person available via email or Facebook messenger whom you can always ask for help, clarifications, tips or additional information regarding non-technical issues online. For example, if you have not ever used messenger on Facebook for voice calls, it is a great opportunity to have a person guide you through this activity and also try it with you. Here are the contact details."

Closing the visit

Before finishing the visit scroll through the filled in responses, and make sure you have entered the interviewee responses in all questionnaire fields.

Arrange a 2-week telephone appointment: *"I would like to call you when you have used MAMEM for 2 weeks, to see what your impressions are. Shall we book a time right now?"*

Before departing, thank the interviewees for their time and for the information about their daily lives, which they shared with you. Emphasize that without their participation this research, which could potentially benefit other people with disabilities, would not be possible. Reassure both respondents that all of their responses will be treated with confidentiality.

Multimodal Protocol

General Information:

One participant will be chosen to perform these series of experiments.

In order to execute these series of experiments the following devices and software are required:

- Devices: EEG device, GSR device, eye tracker device
- Specialized software: GTW, Matlab, OpenVibe

The purpose of this task is to acquire data from multiple modalities. More precisely, data will be acquired concurrently from the eye-tracker device, the EEG device and the GSR device. During these experiments all above devices must be configured correctly and work properly. The EEG experiments are divided into two cases, the ErrPs case and the SMR case. In all cases, the system consists of two general stages, the calibration stage and the testing stage. In the calibration stage, data are collected in order to calibrate and configure the system, while in the testing stage, the system is tested in order to evaluate its performance and to train the user.

General instructions for experimenter:

- Explain to the user the purpose of eye tracker device
- Explain to the user the purpose of GSR device
- Introduce to the user the Enobio EEG capturing device

ErrPs system

During these experiments the user will use the GTW keyboard to write some predefined sentences using his/her eyes. His/her brain signals will be use to provide automatic error correction.

Instructions for experimenter:

- Explain the ErrPs keyboard experiment
- Put the EEG cap on the participant
- Put GSR device on the participant
- Open the ErrPs-designed GTW keyboard
- Calibration Stage:
    - The participant will be asked to type a set of sentences (predefined, asked by the experimenter) for system calibration

- Use the collected data to calibrate/configure the ErrP system
- Testing Stage:
  - The participant will be asked to type a set of predefined sentences with automatic error correction which is encapsulated to the GTW keyboard

The detailed protocol for ErrPs experiment can be found in Appendix 7 of CRF_Phase I. Detailed instructions for the experimenter will be provided in a separate document.

SMR/Tetris system

During these experiments the user will play the Tetris game. His/her eyes and his/her brain signals will be used to control/move various elements of the game.

Instructions for experimenter:

- Explain to the user the Tetris game in general
- Explain to the user how he/she can play the modified Tetris game using his/her eyes and his/her brain signals.
- Put the EEG cap on the participant
- Put GSR device on the participant
- Make sure that:
  - Screen resolution: full HD 1920x1080
- Calibration Stage:
  - Initiate the SMR experiment (OpenVibe)
  - Start the acquisition scenario of OpenVibe for imaginary movement. More information about this can be found in Appendix 8 of CRF_Phase I.
  - The user is asked to think about moving their left/right hand (fist clench) for 40 times each to calibrate the system. There is a visual cue on the screen to indicate the type of movement. After completing the acquisition scenario of OpenVibe files of type *.ov must have been created. These files will be used as input to matlab scripts below.
  - Calibrate/Configure the SMR/Tetris system
    - Convert openvibe files to mat files. This can be accomplished by running the matlab script convertOvToMat.m using as input the <file_name>.ov. The output of this script is a file with name: <file_name>_EEG.mat.
    - Segmentation of EEG raw signals by running the matlab script EEGsegments.m – Input File: <file_name>_EEG.mat , Output File: <file_name>_EEGsegments.mat
    - Using the EEG toobox to train the classifier (script name: trainTetris.m) – Input File: <file_name>_EEGsegments.mat, Output File: <file_name_classifier>.mat

- Testing stage:
    - Run tetrisEEG.m (input file: <file_name>_classifier.mat) in a new instance of matlab
    - Run tetrisEye.m in a new instance of matlab
    - Open the modified Tetris game on GTW
    - Start/Play the modified Tetris game

Detailed instructions for the experimenter will be provided in a separate document.

Week 2 follow up call

After 2 weeks of MAMEM usage the social inclusion interviewer makes a follow up call and asks the following

a) General satisfaction question

On a scale of 10 to 1, how satisfied are you using MAMEM, up to this point? Where 10 means very satisfied and 1 means not at all satisfied: _____

b) Comparative satisfaction question

Which of the following is true of you?

In comparison to my previous digital device, how satisfied are you with MAMEM, on a scale of 5 to 1, where 5 is “by comparison more satisfied” and 1 is “by comparison not at all satisfied”: _____

c) Net promoter score question

Now that you have tried MAMEM for 2 weeks, how probable is it that you would recommend it to a person in your condition on a scale of 10 (would definitely recommend) to 1 (would not at all recommend)?: _____

d) Could you describe your experience? Are there specific issues you have? Could you explain? The possible complaints may have to do with:

- The system itself: we note the complaints and suggest that the technical team is working on optimizing MAMEM.
- Their condition: how their condition influences how they use MAMEM
- In this case we ask whether there is anything on the part of the team that could help them out.
- Inefficient use of the system: they have not mastered any of the features, or they have forgotten how to use any of the features. In this case we provide help via phone and evaluate what needs to be done to support the person.

_____
_____
_____

e) **How could we help? Is there something we could do further, to help with your using MAMEM as best as possible?** If they are not able to articulate what help they may need, and are clearly dissatisfied with MAMEM usage, and it is an issue related

to their not understanding MAMEM use fully, then consider a visit to their home, to find out more and to provide further clarification.

_____

_____

_____

The "After" interview

Social inclusion

Instructions to interviewer: use a card for each of the questions Q1, Q2, Q3, Q4, Q5. *The card presents the matrix of responses. Give the card to the interviewee while you are reading each statement. The person can read the answers, while you are asking a series of multiple statements and the answers will not need to be repeated for each statement. This will speed up the interview time. Examples of cards with answers for Questions 2 and 3 follow below:*

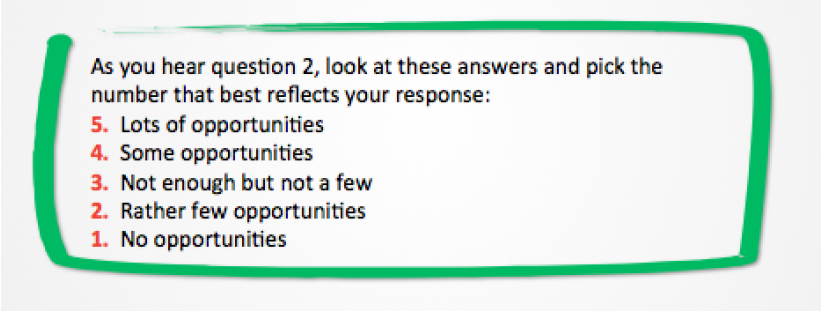


Figure 1: Example of a response card for Question 2

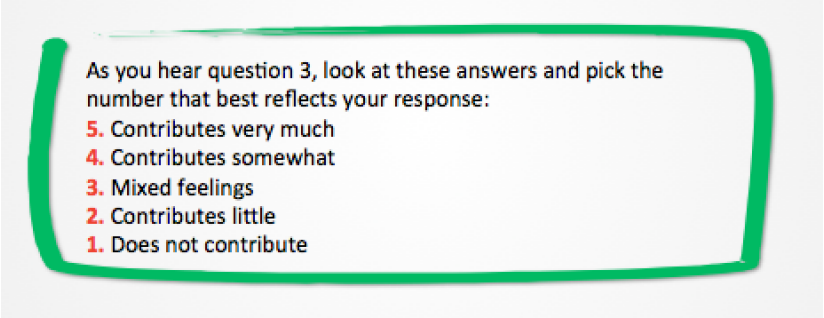


Figure 2: Example of a response card for Question 3

Q1. I will read you some statements that reflect someone's feelings about life, and I would like you to rate how true they are for you on a scale of 5 to 1, where 5 means the statement is totally true for you and 1 means that they statement is not at all true for you

	Very true for me 5	Somewhat true 4	Mixed feelings 3	Not that true for me 2	Not at all true for me 1
Given my disability, I feel included in most aspects of life around me					
I feel more or less optimistic about the future					

I feel I am playing a useful part in society					
I feel that who I am and what I do is valued by others					

Q2. I will read you some digital activities and I would like you to tell me how much each of them contributes to your feelings of inclusion in society and ability to make the most of resources available for your benefit. Please on a scale of 5 to 1, where 5 means that digital activities are totally contributing to your feeling of inclusion and 1 means that they are not contributing at all:

	Contributes very much 5	Contributes somewhat 4	Mixed feelings 3	Contributes little 2	Does not contribute 1
Active use of digital technologies overall					
Active participation in social media like Facebook, Twitter, Instagram					
Active participation in business, education sites like Linked In, Quora, Academia, etc.					
Attending online courses					
Engaging in online job hunting					
Participating in groups, for a, relevant to your interests and needs (health or otherwise)					
Playing online games with others					
Watching /reading content (videos, movies, books, articles)					
Using specialized software and apps relevant to your hobbies (e.g. photoshop, Picasa, etc.)					
Using digital technologies to earn income					
Hiring help online and finding support on issues that concern you					

Q3. I will read you some statements now regarding your digital activities and I would like you to rate how true they are for you on a scale of 5 to 1, where 5 means the statement is totally true for you and 1 means not at all true for you

	Very true for me 5	Somewhat true 4	Mixed feelings 3	Not that true for me 2	Not at all true for me 1
There are people online that I trust to support or help me with my problems					
When I go online, there are people I can turn to for advice, about issues or decisions I have to make					
When I feel lonely there are people online that I can connect with					
I engage often enough in digital/online activities that fascinate and entertain me					
My interactions with people online make me want to try new things					
My online activities make me feel a part of a larger community					
I have opportunities to be active and creative through digital / online activities					
My digital/online activities give me a sense of freedom and choice					

Q4. I will read you some statements now regarding the amount of opportunities you feel you have access to, by engaging in digital and online activities. Please rate the statements from 5 to 1, where 5 means you feel you have access to a lot of opportunities and 1 means there are no opportunities.

	Lots of opportunities 5	Some opportunities 4	Not enough but not a few opportunities 3	Rather few opportunities 2	No opportunities really 1
I feel I have access to opportunities to find employment					
I feel I have access to opportunities to acquire new skills					
I feel I have access to opportunities to					

develop business ideas					
I feel I can pursue promising business contacts					
I feel I can learn more about health issues					
I feel I can communicate and flirt with members of the opposite sex					
I have opportunities to advance my hobbies and my creativity					
I have the opportunity to be a volunteer and to support others meaningfully					

QUEST (Version 2.0)

• For each item, rate your satisfaction with your assistive device by using the following scale of 1 to 5.

• Please circle or mark the one number that best describes your degree of satisfaction with each item.

• Do not leave any question unanswered.

How satisfied are you with,

1. The **dimensions** (size, height, length, width) of your assistive device?	1	2	3	4	5
2. The **weight** of your assistive device?	1	2	3	4	5
3. The **ease in adjusting** (fixing, fastening) the parts of your assistive device?	1	2	3	4	5
4. How **safe and secure** your assistive device is?	1	2	3	4	5

5. The **durability** (endurance, resistance to wear) of your assistive device?	1	2	3	4	5
6. How **easy** it is to use your assistive device?	1	2	3	4	5
7. How **comfortable** your assistive device is?	1	2	3	4	5
8. How **effective** your assistive device is (the degree to which your device meets your needs)?	1	2	3	4	5

• Below is the list of some satisfaction items. PLEASE **SELECT THE THREE ITEMS** that you consider to be **the most important to you**. Please put an X in the **3 boxes** of your choice.

- ☐ Dimensions
- ☐ Comfort
- ☐ Weight
- ☐ Effectiveness
- ☐ Adjustments
- ☐ Safety
- ☐ Durability
- ☐ Easy to use

System Usability Scale (SUS)

		Strongly disagree				Strongly agree
1	I think that I would like to use this system frequently	1	2	3	4	5
2	I found the system unnecessarily complex	1	2	3	4	5
3	I thought the system was easy to use	1	2	3	4	5
4	I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5	I found the various functions in this system were well integrated	1	2	3	4	5
6	I thought there was too much inconsistency in this system	1	2	3	4	5
7	I would imagine that most people would learn to use this system very quickly	1	2	3	4	5

8	I found the system very cumbersome to use	1	2	3	4	5
9	I felt very confident using the system	1	2	3	4	5
10	I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

What comes before and after MAMEM Phase II trials? Brief practical steps on how to deal with potential "psychological distress" of participants

Psychological risks may be particularly significant for our participants. As a result, the researchers may be drawn into extremely complex and highly emotional dilemmas that go far beyond the bounds of scientific research and that may entail major psychological and other risks both to the participant who deals with the devastating condition and his/her caregiver. Nevertheless, MAMEM consortium has to try to consider in advance how these situations will be handled both "before" as well as "after" the study. Research members will ensure that will assist all these individuals, who are both study subjects and patients, after the life cycle of the Phase II experimental period.

What to communicate to a person who sees his/her participation in a BCI study as a last resort?

Be aware that in MAMEM the majority of participants are more "at risk" for having "psychological distress" when the study ends, since they see the BCI as a last resort for communication, while their families may be desperate for a way to prevent the total isolation and dependency they foresee coming. After the completeness of pilot trials and after withdrawing the system, the clinicians of the Consortium will immediately start consulting the patients and caregivers with the best health quality services to deal with and handle the new condition.

Steps on how to deal with potential "Psychological Distress" risk after withdrawing the system from the patients' homes

Suggested strategies include more frequent contacts, calling to follow-up participants in advance of their condition and mental-behavioral status. However, it's of high importance to clarify some "before" steps in order for "after" steps to be smoother.

"Before" Steps

- **Step 1- Build a solid "Patient-Therapist relationship"**

First and most obviously, the personnel conducting Phase II must involve clinicians during the first visit and in the majority of the visits so as to deal with patients' and their caregivers' problems and any queries might emerge (i.e., will I be able to reverse my condition after my participation in this trial?). This will give also the opportunity to build a constructive patient-therapist relationship, which is of high importance for the "after" steps.

- **Step 2- "Patient-Centeredness"-Engage patients in Study from the initial stage**

Since patient advocacy groups now claim that their opinions must have greater influence on the decisions that affect them, which is reflected in the phrase "nothing about me without me", in Phase II trials, we have to engage our patients to our study from the initial visit. It must be ensured that patients receive all the information they need. For the process to work properly, the information provided to patients must be complete, relevant, and easy to understand. Also, we have to clarify and highlight the exact duration of the experiment (~ 30 days). It is essential for participants to understand that the purpose of clinical research is to generate useful information for future patients and not necessarily to achieve a therapeutic benefit (since this cannot be done). Moreover, we have to stress out that the whole equipment is at testing stage and that's why we will withdraw after one month. It is imperative to communicate that we will withdraw the equipment no matter if the operation of MAMEM system was successful or not. The patient engagement is very important since we will give them a motivation to be actively involved during the whole experimental phase.

- **Step 3- Verbal Communication- Physical Visits**

Daily-weekly phone calls as well as physical visits will take place, conducted by the clinicians of the project in order to reassure if they have any problem.

"After" Steps

- **Step 1- Common Questions after the Withdrawal**

At this stage we have to make clear any queries, they might emerge both by patients and caregivers. Some examples of these are:

Examples	Possible Answers
Will my condition get improved after this Phase?	- Explain the MAMEM's goals again in lay language - Unfortunately our study's goal is not therapeutic but to develop an assisting solution for people who would like to use it - We can talk with your doctor and he/she can introduce you some ongoing clinical trials as well as some very interesting non-pharmaceutical activities, from which you may benefit - We don't say straightforward "no" or any other negative statements.
Can I keep the equipment after the end of the phase?	- Unfortunately this equipment has been bought with specific allocated resources only for research purposes by EC. We hope soon to make it accessible in market. However, we will keep you posted if any relevant equipment will be made publicly available. (It is imperative to underline participant's contribution to research study and how this short-term period helped us a lot). - If someone insists on this, we can decide whether we could give him/her a gift (a cheap wearable or something similar)

Can I take part for a longer period in your study? Another one month?	- We highlight how glad we are that he/she enjoyed MAMEM. That's was one of our initial purposes. However, since we have to compare our results with other potential beneficiaries, who need also this equipment we have to follow the timetable we have initially set. In any case we (clinician- patient) will keep in contact and I will remain at your disposal for any clarifications, queries may arise and everything else you may need, or If any change may occur
Why did you choose me? Because I have major problems?	- Explain MAMEM focus with lay language. - We focus in general on people who would keen on using such tools. Our intention was not to select people based on their level of severity but their willingness to use such tools and to provide them our services. - If more medical questions follow, we will advise the participant to contact his/her doctor to answer them
Will you conduct a similar study soon? Can I take part?	- One of our purposes is to continue similar research activities. Your contribution was of high importance for our study. We will keep in contact in case any relevant project may start or any other similar research activity will occur. - We encourage the participant to call us any time if he/she finds something that he/she wants to participate so as to assist him/her if we can.
(Caregiver): What will we do now? He/She (the participant) was very happy during his/her participation and now he/she is devastated	- We will keep in touch to assist you with any issue may occur - He/she (the participant) can take part in some activities, which can be discussed with his/her doctor - We point out that caregiver's behaviour is crucial in these situations. We support the caregiver to deal with any behavioural issues may occur from the patient - We reassure the caregiver that if any similar research activity may start, we will keep them posted definitely. - We can provide them with a list of forums (see below) both for participants and caregivers.

- **Step 2- Accessibility to the Results**

We can give an overview of participant's results after the study and explain both his/her progress and underline his/her contribution to our research study.

- **Step 3- Weekly- Monthly Communication via Telephone**

The psychologists can keep contacting with the patients on a regular basis via telephone in order to reassure if the patients and their caregivers have any issue.

- **Step 4- Psychotherapeutic Approach**

If we notice that the behavioral disturbances (i.e., sleep disturbances, depressive symptoms etc) go beyond what were before the study, when necessary, the physicians as well as the psychologists of the MAMEM, can introduce specific both non- and pharmacological interventions to address the behavioral related problems.

Symptoms	Solutions
Depressive Symptoms/Sleep disturbances following withdraw of the system	- Weekly visits by psychologist for the next 2-3 months - Pharmaceutical Solution?

Adverse Event during the study

To be filled by the Investigator or co-Investigator in case of an adverse event i.e. in case of any medical occurrence in a participant during his/her participation

Investigator/co-Investigator name:

serious Adverse Event (resulted in an illness requiring hospitalization, events deemed life-threatening, persistent or significant disability/incapacity, medically important condition)	❑ yes	❑ no		
Event description:				
Is the event device/treatment related?	❑ Not related	❑ Probably not related	❑ Possibly related	❑ Certainly related

Remarks:

Investigator/Co-Investigator name:	Signature:

Termination Record

To be filled by the Investigator or co-Investigator in case a participant did not finish the full protocol i.e. the participation of a participant had to be prematurely discontinued for any reason.

Characterize the subject's termination status from the study:	❑ Completed	❑ Discontinued

If the participant was prematurely discontinued from the study, indicate all applicable reasons

Do not understand the instructions of the study's personnel	❑ yes	❑ no
Inability to complete at least 50% of the protocol	❑ yes	❑ no
Unable to use the MAMEM platform; e.g. unable to control the computer with brain or eyes after the 1-2 hours of practice	❑ yes	❑ no
Lack of cooperation with the study's personnel	❑ yes	❑ no
Adverse Experience:	❑ yes	❑ no
if yes, specify:		
Other:	❑ yes	❑ no

if yes, specify:

Investigator/Co-Investigator name:	Signature:

Investigator's Statement

To be filled by the Investigator or co-Investigator

This is to confirm that all observations and examinations have been performed according to the Investigational protocol version AI1.

I have carefully examined all entries and all information entered by myself or authorized delegates/representatives is to the best of my knowledge correct.

Investigator/Co-Investigator name:	Signature:

A.2. Ethical approvals for the phase II trials in all three clinical centres

CENTRE FOR RESEARCH AND TECHNOLOGY – HELLAS (CE.R.T.H.)
INFORMATION TECHNOLOGIES INSTITUTE (I.T.I.)
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Web: http://www.iti.gr • E-mail: info@iti.gr

19/09/2017

LETTER OF ETHICAL APPROVAL FOR MAMEM PROJECT (H2020-644780)

GREEK Pilots

The Ethics Committee of Centre for Research and Technology Hellas being informed about the "MAMEM - Multimedia Authoring and Management using your Eyes and Mind" project and the protocol of Phase II trials. The Ethics Committee, within the scope of **MAMEM project (H2020-ICT-2014 - 644780)**, hereby certifies that:

- this study fully complies with H2020 Data protection and privacy ethical guidelines and more specifically with ethical principles and relevant national, union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols to preserve the dignity, autonomy and values of the end-users;
- research participants, who agree to participate in the pilots, will be provided with an information sheet describing their privacy rights along with a brief description of the project activities, the information to be collected, how this information will be used, processed and stored and a letter of consent which they will be asked to sign and return back; and
- all data collected will not be used outside the scope of the project and the retention period of all data and information collected, stored and processed will not be longer that it is necessary to achieve the purpose collected and the period specified within the applicable National Laws and EU Directives.

Therefore, the Ethics Committee of the Centre for Research and Technology Hellas gives approval for the realization of the "MAMEM - Multimedia Authoring and Management using your Eyes and Mind - questionnaires to identify needs, problems and applications" in **Athens by MDA Hellas**, GREECE.

[Full Name of Signing Person]
Konstandopoulos Athanasios

[Position within the Organization]
Chairman of the Board.

[Signature /Stamp]

1.

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ΑΥΓΑΔΟΠΟΥΛΟΥ ΓΕΩΡΓΙΑ
[Full Name of Signing Person]

RESEARCH DIRECTOR
[Position within the Organization]

[Signature /Stamp]

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LETTER OF ETHICAL APPROVAL FOR MAMEM PROJECT (H2020-644780)

GREEK Pilots

The Ethics Committee of Centre for Research and Technology Hellas being informed about the "MAMEM - Multimedia Authoring and Management using your Eyes and Mind" project and the protocol of Phase II trials. The Ethics Committee, within the scope of **MAMEM project (H2020-ICT-2014 - 644780)**, hereby certifies that:

- this study fully complies with H2020 Data protection and privacy ethical guidelines and more specifically with ethical principles and relevant national, union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols to preserve the dignity, autonomy and values of the end-users;
- research participants, who agree to participate in the pilots, will be provided with an information sheet describing their privacy rights along with a brief description of the project activities, the information to be collected, how this information will be used, processed and stored and a letter of consent which they will be asked to sign and return back; and
- all data collected will not be used outside the scope of the project and the retention period of all data and information collected, stored and processed will not be longer that it is necessary to achieve the purpose collected and the period specified within the applicable National Laws and EU Directives.

Therefore, the Ethics Committee of the Centre for Research and Technology Hellas gives approval for the realization of the "MAMEM - Multimedia Authoring and Management using your Eyes and Mind - questionnaires to identify needs, problems and applications" in **Athens by MDA Hellas**, GREECE.

Anagnostis Argyriou
[Full Name of Signing Person]

Senior Researcher
[Position within the Organization]

[Signature /Stamp]

CENTRE FOR RESEARCH AND TECHNOLOGY – HELLAS (CE.R.T.H.)
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19./09/2017

LETTER OF ETHICAL APPROVAL FOR MAMEM PROJECT (H2020-644780)

GREEK Pilots

The Ethics Committee of Centre for Research and Technology Hellas being informed about the "MAMEM - Multimedia Authoring and Management using your Eyes and Mind" project and the protocol of Phase II trials. The Ethics Committee, within the scope of **MAMEM project (H2020-ICT-2014 - 644780)**, hereby certifies that:

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- all data collected will not be used outside the scope of the project and the retention period of all data and information collected, stored and processed will not be longer that it is necessary to achieve the purpose collected and the period specified within the applicable National Laws and EU Directives.

Therefore, the Ethics Committee of the Centre for Research and Technology Hellas gives approval for the realization of the "MAMEM - Multimedia Authoring and Management using your Eyes and Mind - questionnaires to identify needs, problems and applications" in **Athens by MDA Hellas**, GREECE.

Olga Kammona
[Full Name of Signing Person]

Researcher B'
[Position within the Organization]

[Signature /Stamp]

REF. NO: ETH.COM_28

ΑΙΤΗΣΗ

Προς : Επιτροπή Ηθικής και Δεοντολογίας (ΕΗΔ) του Εθνικού Κέντρου Έρευνας & Τεχνολογικής Ανάπτυξης

Τίτλος έργου: « **MAMEM** - Multimedia Authoring and Management using your Eyes and Mind »

Κωδικός έργου: H2020-ICT-2014 - 644780

Ινστιτούτο ΕΚΕΤΑ: ΙΠΤΗΛ

Υπεύθυνος Ερευνητής: Ιωάννης Κομπατσιάρης

Θέμα: Έγκριση από την ΕΗΔ του ΕΚΕΤΑ για το πρωτόκολλο της Φάσης ΙΙ του έργου MAMEM.

Ενημερώθηκα προφορικά για το σκοπό, τα πιθανά οφέλη, την αναμενόμενη διάρκεια και τις αναλυτικές διαδικασίες διεξαγωγής της μελέτης για τη Φάση ΙΙ του έργου, από τον/την υπεύθυνο της μελέτης και εγκρίνω τη διεξαγωγή των πειραμάτων όπως αναφέρονται στο πειραματικό πρωτόκολλο που κατατέθηκε.

Τα μέλη της Επιτροπής:

Ο πρόεδρος της Επιτροπής:

Konstandopoulos Athanasios

Ημερομηνία: 12/09/2017

Αίτηση έγκρισης του Πρωτοκόλου που θα εκτελεστεί κατά τη Φάση ΙΙ των δοκιμών του έργου MAMEM, όπως περιγράφεται στα επισυναπτόμενα έγγραφα:

- **Παράρτημα Α1 - Clinical_Trials_Protocol_PhaseII_MDAHellas**
- **Παράρτημα Α2 - ΠΕΡΙΛΗΨΗ_ΕΡΓΟΥ_ΓΙΑ_ΒΙΟΗΘΙΚΗ_ ΦΑΣΗ-ΙΙ-1**
- **Παράρτημα Α3 - ΕΝΤΥΠΟ_ΕΝΗΜΕΡΩΜΕΝΗΣ_ ΣΥΓΚΑΤΑΘΕΣΗΣ_ ΦΑΣΗ ΙΙ-1**
- **Παράρτημα Α4- Social Inclusion Questionnaire**

Η Επιστημονική Υπεύθυνη του MDA Ελλάς

Μαίρη Φωστηροπούλου

Γενική Γραμματέας του Διοικητικού Συμβουλίου

ΕΛΛΗΝΙΚΗ
ΔΗΜΟΚΡΑΤΙΑ

ΑΡΙΣΤΟΤΕΛΕΙΟ
ΠΑΝΕΠΙΣΤΗΜΙΟ
ΘΕΣΣΑΛΟΝΙΚΗΣ

ΣΧΟΛΗ ΕΠΙΣΤΗΜΩΝ ΥΓΕΙΑΣ
ΤΜΗΜΑ ΙΑΤΡΙΚΗΣ
ΕΠΤΡΟΠΗ ΒΙΟΗΘΙΚΗΣ ΚΑΙ
ΔΕΟΝΤΟΛΟΓΙΑΣ
Συντονιστής Καθηγ.: Δ. Ζαφειρίου
Πληροφορίες:Γ. Σακκά
τηλ.: 2310 999338 Fax: 2310 999293
e-mail: bioethics@med.auth.gr
Κτίριο: Νέων Αμφιθεάτρων
Ιατρικής Σχολής (έναντι ΑΧΕΠΑ)

Θεσσαλονίκη 3.10.2017
Αριθμ. Πρωτ.: 383

ΠΡΟΣ
ΤΗΝ Κ. ΜΠΟΣΤΑΝΤΖΟΠΟΥΛΟΥ ΣΕΒΑΣΤΗ, ΚΑΘΗΓΗΤΡΙΑ

Η Επιτροπή Βιοηθικής και Δεοντολογίας της Ιατρικής Σχολής, του Αριστοτελείου Πανεπιστημίου Θεσσαλονίκης, αφού εξέτασε το ερευνητικό πρωτόκολλο ΦΑΣΗΣ ΙΙ του προγράμματος MAMEM στην υπ΄αριθμ.**9/12.7.2017** συνεδρίασή της, ενέκρινε τη διεξαγωγή της επιστημονικής έρευνας με τίτλο: «***ΔΙΑΧΕΙΡΙΣΗ ΠΟΛΥΜΕΣΙΚΟΥ ΠΕΡΙΕΧΟΜΕΝΟΥ ΧΡΗΣΙΜΟΠΟΙΩΝΤΑΣ ΤΑ ΜΑΤΙΑ ΚΑΙ ΤΟ ΜΥΑΛΟ »***, ΠΟΥ ΔΙΕΞΑΓΕΤΑΙ ΣΤΑ ΠΛΑΊΣΙΑ ΤΟΥ HORIZON 2020.

Με εκτίμηση,

ΕΚ ΜΕΡΟΥΣ ΤΗΣ ΕΠΙΤΡΟΠΗΣ
ΒΙΟΗΘΙΚΗΣ ΚΑΙ ΔΕΟΝΤΟΛΟΓΙΑΣ

Ο Συντονιστής της Επιτροπής

Δημήτριος Ζαφειρίου
Καθηγητής Παιδιατρικής,
Παιδιατρικής Νευρολογίας- Αναπτυξιολογίας

THE STATE OF ISRAEL.
MINISTRY OF HEALTH
THE CHAIM SHEBA MEDICAL CENTER
Affiliated to the Tel-Aviv University
Sackler School of Medicine
TEL-HASHOMER 52621, ISRAEL

מדינת ישראל
משרד הבריאות
המרכז הרפואי המשולב עייש חיים שיבא
מסונף לבית הספר לרפואה עייש סאקלר
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שיבא - מרכז רפואי אקדמי מצטיין

טופס 6 א

אישור ועדת הלסינקי להארכת תוקף ביצוע ניסוי רפואי

לכבוד: **תאריך: 23 מאי 2017**

ד"ר גבריאל זייליג שיקום נוירולוגי ב
מרכז רפואי שיבא

הנדון: **אישור ועדת הלסינקי להארכת תוקף**

לאחר שקיבלנו דיווח על התקדמות הניסוי רפואי, אשר פרטיו מופיעים להלן,
הוחלט לאשר את בקשתך להארכת תוקף האישור לביצוע הניסוי.
אישור זה הנו שלב ביניים בהארכת תוקף הניסוי הרפואי. החוקר יוכל להמשיך בביצוע הניסוי רק לאחר קבלת אישור המנהל (טופס 7א).

פרטי הניסוי

מספר בקשה בוועדה מוסדית: 3268-16-SMC	**סוג הניסוי:** אמ"ר
מספר הבקשה במשרד הבריאות:	
נושא הניסוי (בעברית): MAMEM- היתכנות ושימושיות של מערכת המבוססת על קריאת גלי מוח ותנועת עיניים לשימוש של אנשים עם מוגבלויות קשות בהפעלת מחשבים	
שם מוצר המחקר: BePlus Geodesic EEG System 300 REDn Scientific +GSR	**שם היצרן:** EB Neuro EGI SMI Shimmer
שם היזם וכתובתו: ד"ר מאיר פלוטניק -	**שם נציג היזם בארץ וכתובתו:** ד"ר מאיר פלוטניק -
ניסוי רב-מרכזי בארץ: לא	

מסמכי הניסוי

פרוטוקול הניסוי- שם/מספר: MAMEM Clinical trials	**גרסה:** 4	**תאריך:** 27 / דצמבר / 2016
טופס הסכמה- שם/מספר: טופס 2 ב עברית	**גרסה:** 4	**תאריך:** 27 / דצמבר / 2016
חוברת לחוקר- שם/מספר: MAMEM investegator brouchure	**גרסה:** 1	**תאריך:** 05 / יוני / 2016
מסמך איכות מוצר - שם/מספר:	**גרסה:**	**תאריך:**
טופס 11- גרסה:	**תאריך:**	

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שיבא - מרכז רפואי אקדמי מצטיין

טופס 6 א

אישור ועדת הלסינקי להארכת תוקף ביצוע ניסוי רפואי

1	05 / יוני / 2016

1. **הניסוי הרפואי הנו**

ניסוי רפואי מיוחד, שבסמכות מנהל המוסד הרפואי לאשרו ללא אישור נוסף של משרד הבריאות.

2. **תוקפו של ניסוי רפואי זה יהיה לשנה מיום אישור המנהל של המוסד הרפואי (טופס 7).**

3. **תהליך קבלת הסכמה מחייב מתן טופס הסכמה למטופל על מנת לאפשר לו חשיבה והתייעצות של 24 שעות כפי שמתחייב בנוהל. אישור השתתפות בניסוי קביל אם קוים נוהל זה. זאת למעט מצבים דחופים בהם לא ניתן יהיה להחתים את הנבדק מראש.**

4. **תנאים והגבלות:**

הניסוי מאושר ל- 21 משתתפים בלבד

רק חוקר או חוקר משנה שהנו רופא בעל רשיון תקף רשאי להחתים על טופס הסכמה

מס' הרישום של הניסוי באתר ה-NIH : ללא

שם סגנית יו"ר הוועדה	חתימה	תאריך הדיון	תאריך האישור
פרופ רות הרדוף	פרופ' רות הרדוף מ"מ יו"ר ועדת הלסינקי מ.ר. ע"ש חשיבא	16 / מאי / 2017	16 / מאי / 2017

העתק: מנהל המוסד הרפואי
המחלקה לניסויים קליניים, אגף הרוקחות- משרד הבריאות

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שיבא - מרכז רפואי אקדמי מצטיין

טופס 7 א
אישור מנהל המוסד הרפואי להארכת תוקף ביצוע ניסוי רפואי

תאריך: 23–מאי–2017

לכבוד
ד"ר גבריאל זייליג שיקום נוירולוגי ב
מרכז רפואי שיבא

הנדון: **הארכת תוקף אישור לביצוע ניסוי רפואי בבני-אדם**

בהתאם לבקשתך מיום: **09 / מאי / 2017** ניתן בזה אישור להארכת תוקף האישור לביצוע הניסוי הרפואי לפי מסמכי הבקשה.

פרטי הניסוי

מספר בקשה בוועדה מוסדית: 3268-16-SMC	**סוג הניסוי:** אמ"ר
מספר הבקשה / האישור במשרד הבריאות:	**מספר רישום ב-NIH:** ללא
נושא הניסוי (בעברית): MAMEM- היתכנות ושימושיות של מערכת המבוססת על קריאת גלי מוח ותנועת עיניים לשימוש של אנשים עם מוגבלויות קשות בהפעלת מחשבים	
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ניסוי רב-מרכזי בארץ: לא	

מסמכי הניסוי

פרוטוקול הניסוי- שם/מספר: MAMEM Clinical trials	**גרסה:** 4	**תאריך:** 27 / דצמבר / 2016
טופס הסכמה- שם/מספר: טופס 2 ב עברית	**גרסה:** 4	**תאריך:** 27 / דצמבר / 2016
חוברת לחוקר- שם/מספר: MAMEM investegator brouchure	**גרסה:** 1	**תאריך:** 05 / יוני / 2016
מסמך איכות מוצר - שם/מספר:	**גרסה:**	**תאריך:**

טופס 11- גרסה: 1	**תאריך:** 05 / יוני / 2016

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טופס 7 א

אישור מנהל המוסד הרפואי להארכת תוקף ביצוע ניסוי רפואי

בתוקף ההסמכה שקיבלתי מהמנהל הכללי של משרד הבריאות, לתת אישור כ"מנהל" לעשיית ניסוי רפואי בבני-אדם, במוסד הרפואי מרכז רפואי שיבא, לאחר שהבקשה להארכת תוקף הניסוי אושרה על-ידי ועדת הלסינקי המוסדית בתאריך: **16 / מאי / 2017** , ולאחר ששוכנעתי כי הניסוי הרפואי הנו בהתאם לעקרונות של הצהרת הלסינקי ותקנות בריאות העם (ניסויים רפואיים בבני-אדם) תשמ"א-1980, וכי חוזה ההתקשרות בין היזם, החוקר הראשי והמוסד הרפואי עומד בדרישות הנוהל לניסויים רפואיים בבני אדם, הנני מאשר את ביצוע הניסוי בכפוף לתנאים הבאים:

תנאי האישור

1) הניסוי הרפואי יבוצע לפי העקרונות של הצהרת הלסינקי ועל-פי דרישות הנוהל של ניסויים רפואיים בבני אדם בישראל (נוהל 14, 2016) ודרישות הנהלים הבין-לאומיים העדכניים.

2) הטיפול יינתן רק לאחר מתן הסבר למטופל או לנציגו החוקי והחתמתו על טופס ההסכמה מדעת שצורף לבקשה.

2.1 תהליך קבלת הסכמה מחייב מתן טופס הסכמה למטופל על מנת לאפשר לו חשיבה והתייעצות של 24 שעות כפי שמתחייב בנהל. אישור השתתפות בניסוי קביל אם קוים נהל זה. זאת למעט מצבים דחופים בהם לא ניתן יהיה להחתים את הבבדק מראש

3) כל שינוי, תוספת או חריגה מפרוטוקול הניסוי הרפואי, טעון אישור בכתב של ועדת הלסינקי של המוסד הרפואי ו/או של משרד הבריאות.

4) על החוקר הראשי בניסוי הרפואי לדווח לוועדת הלסינקי של המוסד הרפואי וליזם על כל אירוע חריג רציני (SAE) שארע במהלך הניסוי הרפואי (כמפורט בפרק 13 בנוהל), או על הפסקת הניסוי (כמפורט בפרק 15 בנוהל). ועדת הלסינקי המוסדית תבדוק את הדיווח ותעביר את תוות-דעתה למשרד הבריאות.

5) הארכת תוקף הניסוי הרפואי: **שלושה חודשים בטרם חלוף התקופה המאושרת לניסוי הרפואי**, חובה על החוקר הראשי להעביר דו"ח התקדמות על מהלך הניסוי לוועדת הלסינקי של המוסד הרפואי. הוועדה תודיע על החלטתה לגבי המשך הניסוי למנהל המוסד הרפואי. המנהל ינפיק אישור חדש לניסוי הרפואי.

6) בתום הניסוי הרפואי יגיש החוקר הראשי, לוועדת הלסינקי דו"ח מסכם על מהלך הניסוי ותוצאותיו.

7) האישור ניתן לחוקר הראשי ולמוסד הרפואי המצוינים לעיל ואינו ניתן להעברה לאחר.

7.1 הוצאת כל מידע, כולל מידע על חולים, צילומי הדמיה או דגימות, לגורם חיצוני דורשת הסכם בין המרכז הרפואי שיבא לגורם חיצוני.

8) בניסויים רפואיים הכרוכים במתן שירותים: ביצוע בדיקות רפואיות או באספקת אביזרים, תכשירים רפואיים או משתלים, חובה על החוקר הראשי להודיע לרופא המטפל בחולה בקהילה על השתתפותו בניסוי.

9) אין לפרסם כל מידע אודות הניסוי הרפואי באמצעי התקשורת ההמוניים, כגון עיתונות, רדיו, טלוויזיה, אינטרנט, למעט פרסום בעיתונות מדעית או בכנסים מדעיים, ולמעט פרסום לצורך גיוס המשתתפים בניסוי.

10) אספקת מוצר המחקר (Investigational Product – IP) או האמ"ר למוסד הרפואי בו נערך הניסוי הרפואי היא באחריות יזם הניסוי. אחסונו וניפוקו של מוצר המחקר למטופלים הם באחריות החוקר הראשי. במקרים

THE STATE OF ISRAEL
MINISTRY OF HEALTH
THE CHAIM SHEBA MEDICAL CENTER
Affiliated to the Tel-Aviv University
Sackler School of Medicine
TEL-HASHOMER 52621, ISRAEL

שיבא - מרכז רפואי אקדמי מצטיין

מדינת ישראל
משרד הבריאות
המרכז הרפואי המשולב ע"ש חיים שיבא
מסונף לבית הספר לרפואה ע"ש סאקלר
באוניברסיטת תל-אביב
תל השומר 52621, ישראל

טופס 7 א

אישור מנהל המוסד הרפואי להארכת תוקף ביצוע ניסוי רפואי

של תכשירים רפואיים, פעולות אלו יבוצעו באמצעות בית המרקחת המוסדי, אלא אם כן ועדת הלסינקי החליטה אחרת.

11) שמירת מסמכים: יש לשמור את כל מסמכי הבקשה, האישורים וכל המסמכים הנאספים במהלך הניסוי הרפואי **לפחות 15 שנים מתום הניסוי.**

12) **הגבלות נוספות:**

הניסוי מאושר ל- 21 משתתפים בלבד

רק חוקר או חוקר משנה שהנו רופא בעל רשיון תקף רשאי להתחים על טופס הסכמה

13) תוקף האישור: 19 / יולי / 2018

ב ה צ ל ח ה !

בכבוד רב,

מ"מ מְנהל המוסד הרפואי לניסויים קליניים

פרופ דרור חרץ

העתק:

מנהל/ת בית המרקחת של המוסד הרפואי: (באמצעות החוקר)
היוזם/נציגו בארץ (באמצעות החוקר): ד"ר מאיר פלוטניק(באמצעות החוקר)
המתלקה לניסויים קליניים, אגף הרוקחות-משרד הבריאות