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SMART SOLUTION TO SUPPORT DIGITAL ENTRY OF NEURO-
PSYCHOLOGICAL PATIENT DATA

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ABSTRACT

MUHAMMAD USMAN: SMART SOLUTION TO SUPPORT DIGITAL ENTRY OF NEUROPSYCHOLOGICAL PATIENT DATA

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The purpose of this thesis was to design, implement and evaluate a smart device application for the convenience of neuropsychologists in the field of neuropsychology tests. These tests are primarily conducted to assess the cognitive condition of a patient and decide further medications, if he or she is suffering from Alzheimer disease which is most commonly found type of dementia in elderly people. While conducting these tests, traditionally pen and paper are used to record the patient’s score. Results are then forwarded to the people responsible for data entry job in the clinics to manually enter each patient’s data to their HIS (Hospital Information System).

Another issue with traditional approach is that the clinicians prepare these tests on a computer and then print them before going to patient’s test session. These tests could not be modified without going back to the system, update it and print it again. To address these issues, a smart device application was developed, targeting iOS platform initially, in which the clinicians can design the test form according to their and patient’s needs and modify it anytime anywhere without requiring any exceptional prior knowledge of smart devices. The clinicians can use these pre-designed test form to record the patients’ test results within the application that can be directly saved to the server without involving any other person for manual data entry. This application also enables the clinicians to update patient’s test results if something goes wrong during the session or after it and update them on the server in a convenient way. Requiring the patient’s personal information to keep its test results stored, the application is also providing the feature of managing their personal details. These personal details are transferred using the SSL (Secure Sockets Layer) encryption technology between smart device application and server application for the purpose of security and privacy.
A user study, containing four participants, was conducted to evaluate the effectiveness and performance of the application. In this study, the participants were required to perform a set of tasks in which all features of the application got evaluated. The effectiveness and performance of the application was evaluated against the amount of time consumed by the participants to complete the tasks list compared to number of errors made by them. After performing these tasks, a semi-structured interview session was conducted to obtain the participants’ feedback evaluating the usability of application. According to the results of this study, this solution was found to be a useful application offering a valuable set of features to design, modify and use any kind of entry forms as per the needs of its users. Appreciating the proposed solution, they also suggested some new features and modification to existing ones that may increase user’s interest in it.
PREFACE

There are always some personalities behind the successful accomplishment of any goal and here I would like to mention those all. First of all, I am greatly thankful to my parents and my brother, who supported and encouraged me to apply for higher education degree in information technology under Tampere University of Technology and remained always there till the end of this thesis project.

I would also mention the great Finnish personalities I met, Postdoctoral researcher Heli Vääätäjä my supervisor in the university and Jyrki Lötjönen my supervisor in Combinosics Oy, who encouraged, guided and appreciated me every time I needed them. I learned many things working under their supervision and applied them into my thesis as well as professional life.

Finally, I would like to thank my cousin Zaman Aslam who was always there to help and encourage me whenever I needed him during the whole period of my master’s degree.

Tampere, 28.12.2017

Muhammad Usman
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# ABBREVIATIONS AND NOTATION

## Abbreviations

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<th>Abbreviation</th>
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<tbody>
<tr>
<td>HCP</td>
<td>Health Care Professionals</td>
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<td>ICT</td>
<td>Information and Communication Technology</td>
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<tr>
<td>CDS</td>
<td>Clinical Decision Support</td>
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<tr>
<td>WOW</td>
<td>Workstations On Wheels</td>
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<tr>
<td>COW</td>
<td>Computer On Wheels</td>
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<td>EHR</td>
<td>Electronic Health Records</td>
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<tr>
<td>EMR</td>
<td>Electronic Medical Records</td>
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<tr>
<td>CDSS</td>
<td>Clinical Decision Support System</td>
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<td>AD</td>
<td>Alzheimer Disease</td>
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<tr>
<td>API</td>
<td>Application Programming Interface</td>
</tr>
<tr>
<td>DSM</td>
<td>Diagnostic and Statistical Manual</td>
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<tr>
<td>MTL</td>
<td>Medical Temporal Lobe</td>
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<tr>
<td>NINCDS–ADRDA</td>
<td>National Institute of Neurological Disorders and Stroke–Alzheimer Disease and Related Disorders</td>
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<tr>
<td>CSF</td>
<td>Cerebral Spinal Fluid</td>
</tr>
<tr>
<td>SCD</td>
<td>Subject Cognitive Decline</td>
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<tr>
<td>FLAIR</td>
<td>Fast fluid-attenuated inversion recovery</td>
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<tr>
<td>CAMCOG</td>
<td>Cambridge Cognition Examination</td>
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<tr>
<td>MMSE</td>
<td>Mini-Mental State Examination</td>
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<tr>
<td>RAVLT</td>
<td>Rey Auditory Verbal Learning Test</td>
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<tr>
<td>VAT</td>
<td>Visual Association Test</td>
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<tr>
<td>CFT</td>
<td>Category Fluency Test</td>
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<tr>
<td>TMT</td>
<td>Trail Making Test</td>
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<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>FAB</td>
<td>Frontal Assessment Battery</td>
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<tr>
<td>GDS</td>
<td>Geriatric Depression Scale</td>
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<tr>
<td>DAD</td>
<td>Disability Assessment for Dementia</td>
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<tr>
<td>ELISA</td>
<td>Enzyme-Linked Immunosorbent Assay</td>
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<tr>
<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<tr>
<td>VBM</td>
<td>Voxel-Based Morphometry</td>
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<tr>
<td>TBM</td>
<td>Tensor-Based Morphometry</td>
</tr>
<tr>
<td>MTA</td>
<td>Medical Temporal lobe Atrophy</td>
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1. INTRODUCTION

1.1 Background

Information and Communication Technology (ICT) is a term getting evolved not in months but in weeks and days. [1] There is not any standard definition that represents this term but in nutshell it refers to saving, retrieving and manipulating information as well as transmitting this information in digital form from one platform to other. In the same way, this thesis focuses on developing an ICT solution for digitalizing the traditional manual data entry process being adopted for neuropsychology tests. This solution is an iPad application and named as Neuropsychology Digital Entry.

From the invention of mobile devices that include PDAs (personal digital assistance), tablet computers and smartphones there has been great impact on several fields where medicine is also one of them. Health care professionals now-a-days also prefer to use smartphones/tablet computers for routine as well as special tasks. [2] One of the major inspirations behind the acceptance of mobile devices at point of care by HCPs (Health Care Professionals) considered to be the necessity for improved information as well as communication means. Preferably, HCPs in the field require many types of resources, including:

- Capabilities of Communication: text, e-mail, video conferencing and voice calling.
- Information systems: (EHRs) electronic health records, (EMRs) electronic medical records, (CDSSs) clinical decision support systems, picture archiving
- Means of Informational: guidelines, textbooks, literature related to medical, drug indications
- Software application for Clinics—aids in the diagnosis of disease, medical calculators

Before the existence of smart mobile devices, these capabilities were mostly provided by immovable computers system, which do not address the requirement of mobility in health care services. [2] To fulfill this need, some of the health care systems came up with the portable, wireless mobile stations to keep the information for example Computers on Wheels (COWs) or Workstations on Wheels (WOWs). Evolution in the field of smart devices helped HCPs to have access to better means of information and intelligence at their fingertips, through their tablets and smartphones.

Likewise, Neuropsychology Digital Entry is an ICT-based application which may create a significant convenience for the examiners while examining Alzheimer patient. Alzheimer is a most common phase of Dementia found in the people in which brain suffers from degenerative disorder and results in the memory loss. About 5.3 million of American people are effected by Alzheimer and has become the seventh primary reason of death in there [1]. Primarily there are two types of Alzheimer known in the field. One is Familial AD and the other sporadic AD where AD refers to Alzheimer Disease. Familial AD is comparatively rarely found form of Alzheimer than sporadic AD, it passes down from parents to children and sometimes generations. People younger than the age of 65 are effected by the Familial AD [1] while the other cases of Alzheimer are due to
the sporadic AD that usually takes place after the age of 66 and the patient are tagged as late-life Alzheimer or Dementia patient. The cure of this disease has not been discovered yet but several techniques are under development in order to identify and treat the AD patients at early stage.

Precise identification of AD has confirmed to be difficult to reach. The diagnostic practices now-a-days include neuropsychology tests, neuroimaging techniques and behavioral history assessment [6]. In preliminary tests, the main hurdle in using the CDS tool has been in entering results from clinical and neuropsychological tests manually to the system [3]. At this moment still, the tests are done using a pen and paper almost everywhere. Entering tens of items to the system from different tests is obviously laborious and need plenty of resources specially when there is a long queue of examination filled in forms handed over to the data entry responsible. Secondly there is a strong possibility of mistakes in manual system entries that can result in inappropriate decision making outcomes.

We can foresee three solutions to the problems of manual entry of data to the hospital system and possible human errors while entering this data: 1) Dedicated automatic tools are developed for reading the forms. This is not, however, a very modern solution on these days although doable. This solution would still require that somebody scans the documents and there can be issues in developing a robust automatic pattern recognition tool. 2) Fully electronic version will be adopted in different hospitals. Hospitals are, however, used to certain tests and transferring those to electronic versions is not straightforward (e.g. some drawing tests). In addition, the most demented cases and elderly people in general will certainly have more challenges with an electronic version than with a paper version. 3) The test itself is done still on paper but the specialist enters the summary of results to an electronic form. Discussions with neuropsychologists have revealed that using a laptop computer between the patient and specialist during tests sessions is out of question but a tablet could work.

1.2 Objective

The goal of this thesis is to digitalize the way of submitting patients test results directly from the examination environment to clinical server as well as making it possible for neuropsychologists to generate new or update the already generated forms at runtime. Moreover, one of the goals is also to reduce the number of clicks (Taps on touch screen) or human work done as much as possible while saving the test results or fetching them from server.

The developed solution/application will possibly fulfill all of the above-mentioned goals. The user would easily perform the desired tasks required for the test conduction even having very basic knowledge about information technology or smart devices.

To achieve these goals the following research questions required to be focused on:

1. How can the patient’s examiners be provided a digital mean to submit collected data to HIS (Health Information System)?

2. How can be the work done required to operate smart solution be minimized while patient is being examined?
3. How can the examiners be enabled to design test forms according to their needs and update them whenever they want, without affecting the previously collected data against old version test forms?

4. What technologies are potential and can be used for cross platform development purposes if there comes a need to release a new version supporting other platforms in addition to iOS?

1.3 Limitations

- The purposed smart device solution will be used in the real Alzheimer patient tests environment which occurs only between an examiner and the possible patient. This will be the main hurdle that could be faced to evaluate the desired solution in real time environment where no other individual is allowed to sit in and evaluate their designed system when doctor is evaluating the patient.

- Currently the application is supposed to be developed for iOS operating system but in future there is a possibility to develop the solution of similar nature for other platforms e.g., Android, Windows. There is a doubt of having different kind of views and controls provided by the platforms to use them in the solution which can affect the user experience of application e.g., dialog views, back-buttons, dropdown lists etc.

1.4 Thesis outline

The thesis contains following chapters having possible sub-chapters under them.
1. **Introduction part** – gives an overview of this thesis mentioning how information and communication technology is affecting the field of medical along with other professions. What problems are being faced by the health care professionals while performing AD diagnosis tests and what can be the possible solution to address these issues.

2. **Background** – part explains what are the similar kind of systems already available in the market or under research phase. What deficiencies are still there to be focused on regarding the diagnosis methods of Alzheimer disease. There are also many clinical and non-clinical techniques discussed in detail for the diagnosis and treatment of other dementia syndrome.

3. **System implementation** – explains how the solution looks like, what are the navigational flows and what features have been incorporated in it. This also tells what technologies and architectures have been followed while developing the smart device application as well as server side application.

4. **User study** – this chapter illustrates what research methodology has been adopted and how it was executed. It also discusses the participants’ recruitment process and what devices and tools were used for this study.

5. **Study Results** – reports the outcomes of different parts of user study which includes accomplishing a list of tasks and conducting a semi-structured interview session subsequently.

6. **Discussion** – chapter interprets and describes significance of the findings resulted after the development and evaluation phases of system. It analyses the outcomes of the study as well as to what extent the research statements of this project have been targeted.

7. **Conclusion** – part winds up the evaluation and conclusion statements based on the experiences and feedback of the participants. It also discusses the future work for the application which either was suggested from the participants or organization responsible for the development of project.
2. BACKGROUND

This chapter describes numerous cognitive impairments including Alzheimer disease and the means being adopted to diagnose these impairments.

2.1 Cognitive Disorders

Brain is the most important and central part of our body’s internal and external functions. It is directly related to each part of our biological system. These biological functions also include learning and remembering (keeping in memory) which are processed by this brilliant piece of flesh. These functions take place by using multiple segments of our brain that work all together and make it possible to perform a single function. These sections of brain are closely connected to each other and that is why the abnormality or impairment in one or more of these interconnected and complex division may cause damaging as well as long lasting negative results. These results may prompt the symptoms of neurodevelopmental or neurodegenerative disorders [66].

2.1.1 Types of cognitive disorders

Cognitive disorders are said to be the impairments or disorders in which one’s learning, memory or motors skills do not work as normal people. There are many different means of cognitive disorders under the hierarchy of dementia disease which include Alzheimer’s disease (AD), dementia with Lewy bodies (DLB), vascular dementia (VaD), frontotemporal dementia (FTD), Parkinson’s disease (PD), strokes and other disorders that instantiate dementia. These cognitive disorders or impairments upset or completely destroy a person’s memories and learning abilities [66].

2.2 Diagnosis and treatments

2.2.1 Diagnosis of Vascular Dementia (VaD)

Most of the diseases mentioned above that generate the cognitive disorders in an individual are partially or totally curable depending on the stage of diagnosis, the early the better chances to cure. Considering the vascular dementia (VaD), there are numerous diagnosis mechanisms offered by International Classification of Disease (ICD), National Institute of Neurological Disorders and Stroke — Association Internationale pour la Recherche et l'Enseignement en Neurosciences (NINDS-AIREN) and Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR). All these criteria recommended by the researches got three requirements in common. To execute these methods they need (a) dementia impairment or cognitive disorder revealed by neuropsychological analysis, (b) the medical record of stroke and other symptoms of cerebrovascular syndrome validated by neuroimaging (c) short-term connotation among the cognitive indicators and cerebrovascular complaint. The use of different medications containing statins, memantine, galantamine and donepezil play a significant role to cure vesicular dementia [67].
2.2.2 Diagnosis of Frontotemporal Dementias (FTD)

Frontotemporal dementias (FTD) are relatively complex in clinical and pathological way and usually considered responsible for approximately ten percent of total dementia cases found in people. Observations reveal that it usually strikes a person at the beginning of year 58 of their age. For the diagnosis of FTD, MRI reports and T1-T2 weighted brain images perform significantly key role to examine and diagnose the problematic segment of brain [68].

![MRI brain images revealing temporal atrophy with marker points](image)

*Figure 2 - MRI brain images revealing temporal atrophy with marker points [68]*

2.2.3 Diagnosis of Parkinson’s disease (PD)

Parkinson’s disease which is also known as PD belongs to the neurological degenerative illness. Initial stages of PD are related to the weak motor skills that include stiffness, tremor and less smooth and unusual movements. The impairment gets more dangerous with the progress of PD and can generate dementia and gait imbalance that can result in falling. For the diagnosis of this disease, there are numerous techniques and mechanisms that differentiate in the diagnosis procedure, performance and cost compared to each other [69]. These methods include:

- Clinical diagnostic criteria
- Genetic testing
- Autonomic function testing
- Olfactory tests
- Drug challenge tests
- Neurophysiological tests
• Neuropsychological tests
• Neuroimaging

Correct identification of Parkinson’s disease’ clinical features is still the basic requirement for its diagnosis. Certain examinations (neuroimaging, olfactory and genetic studies) play a key role to analyze and confirm the identification while some of them may possibly be adopted soon to diagnose issues in a pre-symptomatic stage of the illness [69].

### 2.2.4 Diagnosis of Dementia with Lewy Bodies (DLB)

While considering dementia with Lewy bodies (DLB), it is a disease which is under-recognized and almost twenty percent of dementia cases are related to this cognitive impairment. Although the diagnosis of DLB is more complex as compared to the other dementia diseases. The diagnostic indicators and symptoms of dementia with lewy bodies are of worth only when appear at early stage of disease because the similar kind of symptoms begin occurring at later stage of other dementia disorders [70]. The methods used for the diagnosis of this disease include MRI, fluorodeoxyglucose (FDG)-positron emission tomography (PET), amyloid PET and DaTScan studies [71].

### 2.3 Diagnosis of Alzheimer disease (AD)

#### 2.3.1 Stages of Alzheimer disease

One of the most common type of cognitive impairments behind dementia is usually identified to be Alzheimer disease. There are different progressive stages of Alzheimer disease naming, mild cognitive impairment (MCI), Preclinical AD, Prodromal AD, mature stage of AD. These all stages along with their behavior of occurrence have been defined later in Figure 3 - Glossary of terms.

#### 2.3.2 The rule of proposed diagnosis criteria

Differential diagnosis of AD dementia is a complex job. Principles of data-driven medicine based Clinical decision support systems (CDSS) could provide a systematic and objective way to aid clinicians for better exploiting all data acquired from patients. A unit got formed during the year 1983 by National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer’s Disease and Related Disorders Association (NINCDS-ADRDA) to standardize the principles as well as define clinical diagnosis mechanism of Alzheimer’s disease (AD). This unit focused on the concerns of clinical examination, history of medical, examination related to neuropsychology along with laboratory assessments to construct a report that got publically published by July 1984 [49]. For the purposes of research, Alzheimer disease’ (AD) diagnosis follows proposed principles by groups (DSM-IV-TR) [21] and (NINCDS–ADRDA) [22]. Their criteria remained unanimously implemented, very beneficial and continued in its original form without alterations for over a quarter century. Nevertheless, in 27 years, now the imperative enhancements in the conceptualization of AD, in capability to identify
AD of pathophysiological process together with the revolutions in understanding about clinical spectrum of the disease took place.

### 2.3.3 Amendments in the criteria

The major points of the offered criteria which needed amendments are:

1. Deficiency of acceptance of unique evidences of additional dementing symptoms that take place in similar aged people as these could not be utterly acknowledged years ago including extensive characterization of behavior variant frontotemporal dementia [52–54], vascular dementia [51], Dementia with Lewy bodies [50] and primary progressive aphasia [55].

2. The results containing cerebrospinal fluid (CSF) assays, magnetic resonance imaging (MRI) and positron emission tomography (PET) imaging were not included while making important clinical decisions. The detailed approach to incorporate biomarkers and join them together in the diagnostic procedure of MCI and AD [56] for better results.

3. There was a well-accepted point that the patient of AD dementia always get diagnosed with memory impairment which causes cognitive deficit while the later experiments exposed that there can be numerous nonamnestic appearances due to development of AD in pathophysiological way, the condition related to posterior cortical atrophy [57] and logopenic-primary progressive aphasia [58] were usually recorded in the patients.

4. Deficiency in the data regarding AD genetics. The alterations in 3 genetic factors—presenilin-1, presenilin-2 and amyloid precursor protein instigate a premature arrival of inherited AD [59].

5. The age limits that were proposed for the AD dementia diagnosis. The experiments gone through in recent decades exposed that AD dementia of people with the age of more than forty years is not different from old people in its pathophysiology way [60]. In the people of more than ninety years’ age AD dementia is also the portion of similar range as that of younger people, however clinical pathological associations got reduced [61].

6. Tremendous diversity in the existence of conceivable AD dementia categories, which also include a set of people who might can now be identified having “Mild cognitive impairment (MCI).”

The process of diagnostic having two steps 1. Early stage diagnosis of syndrome of dementia and 2. application of criteria following clinical features of AD phenotype is gone through to make these proposed criteria acceptable. Criteria based on DSM-IV-TR involve both a memory disorder plus deficiency in one or more additional cognitive area, these both factors/diseases fully or partially effect the daily life activities and social features. Daily life activities impairment is now to have the threshold in order to start diagnosis for dementia if it goes beyond the limitation of abnormality in cognitive domain.

### 2.3.4 Result of amendments in proposed criteria

The clinical criteria for the diagnosis of probable AD based on NINCDS-ADRDA no more demand the evidence of occupational or social functioning interference however they still are containing the conditions of inception of AD and that there is a problem
going on with the basic systematic brain tasks which most probably may affect the cognitive deficits and progression of memory. The criteria being accepted currently is supporting the AD diagnosis within a clinical domain that requires no biomarkers for definitive diagnosis. A perfect diagnosis of AD can only be made by following the criteria based on NINCDS-ADRDA if there requires the confirmation of histopathological clinical diagnosis [22].

The NINCDS–ADRDA criteria was published in 1984 and since then there has come a great advance in the biological basis of AD elucidation allowing the understanding of disease process in unprecedented way [23]. AD phenotype is not anymore expressed in terms of exclusionary, but characterized in more explicit way on a phenotypic basis. The distinctive biomarkers related to any disease can now be visualized even structural changes in brain can be seen in MRI with the help of early and detailed use of the medial temporal lobe (MTL) [23]. The main intention behind this evolving early diagnosis of AD has been extreme research interest for characterization of early stages which precede the presence of crossing functional disability dementia threshold. Prodromal AD (figure 2) should be diagnosed and well treated within the heterogeneous and broad cognitive functioning state that lies outside of the limit of normal ageing [23]. Nosological terms have described this state in wide range that include age-related memory destruction, age-related decline in cognitive domain, insignificant cognitive disorder, disorder related to neurocognitive and impairment in cognitive and neurocognitive functionality [24–29]. One of the frequently known term in the diagnosis of mental disorder in people having subjective or cognitive memory symptoms and impairment in cognitive or objective memory of people while their activities related to daily living being normal is known as Mild cognitive impairment (figure 3). Advancement to the methods of clinically diagnosable dementia is taking place at higher rate in mild cognitive impairment as compared to the unimpaired one, however clearly it is still inconsistent clinical result at follow-up [30]. There is still a great need to refine the definition of AD for the reliable and early stage identification of disease.
2.3.5 Clinical tests

Clinical and neurological tests for probable cognitive disorder diagnosis evaluate motor and sensory skills, coordination and equilibrium, the function of one or more cranial nerves, vision, mental status as well as the variations in one’s temper or behavior.

2.3.5.1 Computed tomography Scan - CT Scan

CT Scan which stands for computed tomography is an easy executable and trouble-free test used to develop fast, well-rendered two-dimensional images of brains and other organs. Neurological computed tomography is being widely used scan to observe the brain and spinal cord. The images produced by this scan can significantly help to identify brain and vascular abnormalities, cysts and tumors, encephalitis (inflammation of brain), spine stenosis (contraction of spine canal), clot of blood or intracranial bleeding because of stroke, brain injury due to shock or fracture on head, and other complaints and impairments. Numerous neurological impairments appear with similar kind of features while CT scan can assist in better diagnosis by distinguishing the region of brain which got disturbed due to disorder [72].
2.3.5.2 Functional magnetic resonance imaging - fMRI

In fMRI (functional magnetic resonance imaging), real-time images of blood flowing within the specific area of brain are developed by using the blood’s magnetic features. The fMRI may clearly locate the regions of the brain which turn into active state and make it noticeable for how long those areas stay in that state. These magnetic resonance images can also reveal if the brain activity inside an area arises concurrently or sequentially. This MRI test is considered to be very helpful while assessing the damages in brain lead by head injury or degenerative impairments for example Alzheimer’s disease and to detect and observe several neurological complaints which include stroke, sclerosis and tumors [72].
2.3.5.3 Positron emission tomography – PET

Positron emission tomography tests which in short are called as PET scans are adopted to generate 2D and 3D brain activity images by evaluating the radioactive isotopes which are inoculated into the blood flow. Images of the brain developed by PET scans play a key role in the detection or highlighting the diseased/affected tissue and tumors, identify the growth of tissues, revealing flow of blood, assessing patients who may experience seizure impairments which make them not to improve by clinical therapy and the patients having any memory impairments. PET may be adopted as a continuation diagnosis process to CT or MRI scans to provide the physicians better exposure of particular regions of brain which can be affected by any neurological impairment [72].

![PET brain scan](image)

**Figure 6 - PET brain scan [73]**

2.3.5.4 Cerebrospinal fluid - CSF

Cerebrospinal fluid known as CSF examinations are extensively used in the clinical diagnosis procedures of neurodegenerative disorders and are considered to be the excellent tools for early diagnosis and prognostic monitoring. Numerous observations reveal that CSF can reflect the pathological modifications in the central nervous system (CNS) [74] because of its exclusive affiliation with peripheral blood system [75]. Latest researches for the diagnosis criteria of Alzheimer’s disease (AD) recommend cerebrospinal fluid (CSF) biomarkers result for better evaluation [77]. This is believed to be a major breakthrough in the AD biological diagnosis procedure which relies on a decline of amyloid peptides (Aβ42), upsurge of tau and phosphorylated-tau (p-tau) proteins in CSF. The variations in CSF were discovered many years before the appearances of clinical symptoms in certain scenario [76] however, the resulted value of CSF investigation is not restricted to clinical diagnosis but also can offer appropriate acumen while understanding the pathogenic principles/mechanisms about dementia.

2.3.6 Computerized test batteries

2.3.6.1 Cambridge Automated Neuropsychological Test Battery - CANTAB

The cognitive assessment system based on CANTAB test battery was first introduced in 1980s to evaluate the cognitive function in dementing and old people [87]. This test
battery has developed a huge normative data set and being extensively used in clinical researches having 1,300 or more peer reviewed articles in support of its usage [88]. This CANTAB system is a test battery with semi-automated functionalities and can be run on any kind of traditional computer. In recent times, it has also been developed/updated in a way to run on bigger touchscreen devices e.g., tablets, iPads etc.

The currently available version of CANTAB-Eclipse consists of twenty-five assessment tasks intended to evaluate different sections of cognitive areas that can be categorized into seven comprehensive groups of tests: executive functions, planning and working memory, verbal/semantic memory, visual memory, attentiveness, response control and decision making, social cognitive sense, and familiarization/screening [89].

![Figure 7 - CANTAB neuropsychological tests [88]](image)

The tasks included in CANTAB tests are the most definite and extensively used computer based assessment tools of cognition. These tasks may either be ordered independently or as a battery to evaluate certain features of cognitive-function in different curative areas. CANTAB is independent from language and cultural barriers, non-invasive and does not require any kind of technical information/experience or prior knowledge of computer/tablet-devices which makes them more convenient for huge, multi-site researches and divergent groups of participants [89].

### 2.3.6.2 Brief Cognitive Assessment Tool (BCAT)

The BCAT technique is a uniquely applied concept to assess the cognitive function of people who have memory and other cognitive impairments. It was designed for every domestic and clinical environment in which cognitive-functioning and cognitive disorder is an issue to be cured or evaluated. BCAT approach combines multiple distinct subsystems: BCAT brain-psychotherapy program, BCAT test system, MemPics booklets and the BCAT working-memory practice sheets. These all systems are person centered programs which are used by HCPs, caregivers, patients and other stakeholders. The test system quickly, yet broadly, evaluates the present cognitive-function. The resulted scores of tests can be used to conclude certain brain psychotherapy mediations and modules to cure.

### 2.3.6.3 CDR computerized assessment system

The Cognitive Drug Research system or CDR is a concise, multiple trail based 9 digital computerized tests battery for cognitive assessment. Numerous alternating forms which are available in many different languages make this battery of tests suitable for multinational clinical trials. The battery is based on computer fed algorithms or sets of rules to
set up different test forms and randomize these throughout the recurring assessment tests, so that every time in a scheduled test each applicant accomplishes a unique test form. The simplest design consisting of two response buttons reduces the motor element while performing the task and facilitates its usage for the people having impairment related to motor control [90].

The CDR-system is based on different modules which include tests regarding information processing and response speed (Digit vigilance tasks, Choice reaction time, Simple reaction time), working memory and executive functions (Semantic reasoning, Spatial working memory exercises, Articulatory working memory tasks), visual episodic and verbal memory (immediately and delayed word recall [administrator is the one recording verbal responses], Word, face and picture recognizing exercises), motor control (postural stability tasks and tapping tasks). The sensitivity index (SI) ranging from 0 (risk performance) to 1 (ideal accuracy) is computed for the recognition and working memory tasks [90].

2.3.6.4 CNS Vital Signs

The CNSVS is a concise clinical assessment battery which consists of 7 tests. This test battery contains the tests which neuropsychologists are using very commonly and considered to be very consistent and effective according to them. These tests target the various domains of cognitive area and also popular due to their good sensitivity to most of the reasons resulting mild cognitive dysfunction. These tests include Continuous performance test (CPT), Symbol digital coding (SDC), Finger tapping test (FTT), Shifting attention test (SAT), Visual memory (VIM), Verbal memory (VBM) and Stroop test (ST) [93].

Visual memory and verbal memory tests called as VIM and VBM respectively are the editions of Rey Visual Design Learning Test and Rey Auditory Verbal Learning Test. These tests are not the tests of recall but based on the recognition features. Correct results from VIM and VBM are calculated to get combined memory domain total points [92].

The FTT is a part of main evaluating tests which Halstead–Reitan test battery contains however many tests alike FTT did exist and adopted by the psychologists of 19th century also including the popular names Cattell, Wundt, and Galton. SDC test is developed following the symbol digit modalities test which is the digital computer
based modified version of Wechsler’s digital symbol substitution test. The aggregate of the taps on left and right keys from Finger tapping test and total correct results of SDC produces a combined psychomotor speed result [92].

Stroop test from CNS vital signs referred as ST contains 3 sections which produce simple to complex reaction time tests gradually. Taking the average of 2 complex reaction time tests’ results provides the total for ST and this calculated score may also be referred one’s speed for processing the information [92].

SAT determines the quick and accurate shifting ability of a person from one set of instructions to the other. The other computer based batteries as CogState, NES2 and CANTAB also contain attention shifting evaluation exams. Many other tests featuring Color-shape similar to shifting attention test got adopted for the studies related to cognitive imaging. The cognitive flexibility domain score is calculated through adding all accurate responses and subtracting all the mistakes/inaccuracies made while participating in Stroop Test and SAT [92].

The CPT test is used to measure the sustained attention or vigilance. The resulted total for complex attention is calculated through summing up all the errors made while participating in ST, SAT and CPT [92].

2.3.7 HCl based diagnosis systems

2.3.7.1 Gesture Recognition-Based Serious Games

In this project, a set of gesture recognition based 3D games was developed using 3D depth camera, openNI (open natural interaction) and gesture recognition functions library. With the help of these gesture based games, the possibilities of memory impairment and other dementia symptoms can be prevented. This system is designed to recognize the body gestures of the user and increase the brain usage and activities to prevent dementia. Discussing the key components of this system, the first is Kinect type 3D depth camera which distinguishes the objects based on the depth data obtained from an infrared sensor. These cameras are also more stable as compared to the regular cameras under the variety of lights [97].

OpenNI is a software development kit containing a number of APIs used along with the 3D depth camera. This SDK provides features regarding RGB image acquisition, environment set-up of the camera, infrared light source control and 3D depth image acquisition together with middleware for the detection of user presence, location of its joints and tracking its direction.
While standing in front of the 3D camera, the sensation of its presence, differentiating it from the background, locating and mapping its joints, this is all done by the 3D depth camera along with openNI SDK, but the movement of these joints and interpreting different gestures from this movement is done the Motion-X library. This library is developed by researchers working in this project in which they predefined the movement patterns to recognize different gestures associated with 15 joints of the users.

Table 1 - Pre-defined movement patterns in Motion-X library

In this project, there are 4 3D games developed to prevent the dementia syndromes. These games have been named as memory practice game, reasoning skill practice game, calculation practice game and spatial recognition practice game. In memory practice game, the user needs to find two identical animals which are hidden under the brown boxes. There are 16 identical boxes having 8 sets of identical animals hidden under them. In start, the user is given 5 seconds to memorize the location of as many animals as possible and then these animals are covered by the boxes. The user can select and
reveal the boxes with the help of the mouse\_controls() and arm\_forwards() functions defined in the above table (Table 1 - Pre-defined movement patterns in Motion-X library). This game is very effective to increase the memorizing skills.

![Figure 10 - Showing and hiding animals](image)

In reasoning practice game, the user is entered to a level of maze in which he or she needs to find an exit within a specific period of time. The walking and direction changing movement (Figure 9 - Locating user joints and sensing its gestures) is interpreted to the gesture and applied to the avatar of the game. This game is useful to increase the spatial recognition and reasoning skills.

The calculation practice game has a gameplay in which a set number-marked boxes play the role of a supporting ground hanging in space and user needs to jump from one box to the other. The value or score of the box, where user jumps, is added to the total score of the user while the target is to achieve required score in a certain period of time.

![Figure 11 - Spatial recognition gameplay](image)

In spatial recognition practice game, there is a 3D cube rotating in the middle of the screen and at all the four corners of the screen there are 4 static images shown. Each side of 3D cube resembles to one of the static images at the screen corners. The user is required to select the right image after matching it with the current side of 3D cube while it is rotating. This game can be very efficient in sharpening the spatial recognition skills of a person. The scores of all these games are calculated and represented in the form of chart to assess the performance of the user on daily basis so the current results can be compared to the previous ones.
2.3.7.2 Personal Assistant Robot (PARO)

The robots to assist the elderly people to become socially interactive have been developed and found very effective in recent years [98]. These robots are normally personal companion robots. Several studies, including anecdotal reports, have revealed that the therapies based on robotic assistance can be adopted for dementia treatment in elderly people due to their cost efficiency compared to traditional therapies [100].

![PARO therapeutic robot](image)

**Figure 12 - PARO therapeutic robot**

Personal assistant robot (PARO) is a socially assistive, pet-type therapeutic robotic toy having the appearance of a baby harp-seal which is supplied containing special types of sensors inside it, including posture, light, tactile, audition and temperature. Therefore, it reacts to several stimulations (holding and striking) provided by the user and also recognizes voice direction to them. PARO has the ability to remember its name and learn the behavioral reactions that make the user feel pleasant. These capabilities have been achieved by implementing artificial intelligence in the development of its software application. This robot was primarily designed and developed by Shibata et al [99], and has been adopted with promising and positive results since 2003 in several countries which include Denmark, Japan, United States, Italy Canada and many other from Europe. During 2009, PARO got licensed as a category of neurological therapeutic equipment by the Food and Drug Administration (FDA) in USA (reg. no: 3009118691) [98].
Different experimental studies reporting numerous positive effects of PARO based therapy in individuals with dementia and other brain syndromes have been conducted [98]. Design of PARO having the characteristics of an animal was based on the studies revealing the fact that animal-assisted therapy is very useful to change the mood positively, and enhance social communication and interaction among individuals with dementia.

2.3.8 Neuropsychological tests

2.3.8.1 Mini-Mental State Examination - MMSE

The Mini-Mental State that is also named as MMS or MMSE was prepared to use in the clinical environment by physicians for the cognitive grading of patients. This test was first publicly available in 1975. During that period, there were several lengthy batteries of psychological assessments and many short measures for the usage in clinical environment [78], but all these were not usually included into daily assessment practices. At that time, there was great need of a measuring tool which could be the middle ground in the patient assessment procedure and legitimated quickly and acceptably [31].
The time when this test was first published, publishers and creators of this test could not have perceived that how popular its usage would become, proved by the speed with which huge numbers of papers featuring it got published and also translated into several languages [31]. MMSE is used as a utility service to the diagnostic procedure of dementia and for checking the development or progress of the cognitive disorder in patients.

Mini-Mental State Examination (MMSE) is one of the frequently used test battery for the identification of mild cognitive impairment (MCI) and dementia in both research and clinical environments [31]. This is a 30-points measuring tool which offers a concise way of assessing function in numerous cognitive domains. Though MMSE resulting score relates with but does not declare dementia. The patient’s score below 24 is usually taken as a warning of probable dementia while the score between the 24 and 27 can direct towards MCI. This neuropsychological test shows rationally high levels of specificity and sensitivity while differentiating non-demented persons from mild or full-blown dementia [79]. Several researches have revealed that the MMSE got a low sensitivity to MCI and this has directed to the opinions that scores over 24 are not very helpful in the assessment process [80] while on the other hand, many studies have addressed its adequate levels of sensitivity and specificity to be accepted and recommended its continual use in assessment of MCI [81].

This test includes different kind of questions under their corresponding categories e.g., orientation, registration, recall, and language etc. related as shown in the Figure 14 - MMSE test form. Each question in each section holds a specific weight according to its relevance to the diagnosis measure. Considering the above mentioned Figure 14 - MMSE test form, this test holds the total of 30 points summing up all the questions’ weight. In the first section of orientation, there are two questions in which the possible patient will need to answer/name the asked sub-questions and if he/she answers all mentioned sub-questions right, the total score of this section would be 10, but if there are

<table>
<thead>
<tr>
<th>The mini mental state examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orientation</td>
</tr>
<tr>
<td>Two, month, day, date, season</td>
</tr>
<tr>
<td>Countryside, county, town, hospital, ward (clinic)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Registration</td>
</tr>
<tr>
<td>Examine names three objects (for example, apple, pen, and table)</td>
</tr>
<tr>
<td>Patient asked to repeat objects, one point for each</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Attention</td>
</tr>
<tr>
<td>Subtract 7 from 100 then repeat result, stop after five subtractions (Answers: 93, 86, 79, 72, 65)</td>
</tr>
<tr>
<td>Alternatively if patient errors on subtractions then to spell word backwards: D I F O W</td>
</tr>
<tr>
<td>Score best performance on either task.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Recall</td>
</tr>
<tr>
<td>Ask for the names of the objects learned earlier.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Language</td>
</tr>
<tr>
<td>Name a pen and a watch.</td>
</tr>
<tr>
<td>Repeat: his, her, and both.</td>
</tr>
<tr>
<td>Give a three stage command; Score one for each stage (for example: “Take this piece of paper in your right hand, fold it in half and place it on the table.”)</td>
</tr>
<tr>
<td>Ask patient to read and obey a written command on a piece of paper stating: “Close your eyes.”</td>
</tr>
<tr>
<td>Ask patient to write a sentence. Score correct if it has a subject and a verb.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Copying</td>
</tr>
<tr>
<td>Ask patient to copy intersecting pentagons.</td>
</tr>
<tr>
<td>Score as correct if they overlap and each has five sides.</td>
</tr>
</tbody>
</table>

Total score: 30

**Figure 14 - MMSE test form**
partially right answers then the score can be any number between 0 and 10 following the right number of answers. This is the way MMSE test is taken and the gathered data then analyzed to evaluate the patient’s cognitive situation.

2.3.8.2 The Consortium to Establish a Registry for Alzheimer's Disease - CERAD

The Consortium to Establish a Registry for Alzheimer's Disease (CERAD) examination battery was formerly introduced to assess the cognitive disorders due to the initial stages of Alzheimer Disease (AD) [82]. This test was first developed in 1980s to establish standardized and substantiated measures for the diagnosis of AD. After the introduction of CERAD, it became a widely-used evaluation tool in clinical environments for cognitive disorders in general, though few researches have been done on its capability to assess the functional deficiency and dementia in many syndromes than AD. High re-test reliability, longitudinal validity and inter-rater agreement are the main discovered strengths of CERAD battery [83]. This test consists of several sections assessing different cognitive areas: memory strength, verbal grasp, language functions, visuospatial functions, delayed recall, executive function and recognition memory.

Its verbal memory section, particularly delayed recall became very helpful while discriminating between healthy cases the ones having mild AD. The patients with AD also face a fall in recognition memory and they do not appear to show interest in the emotional content that is someway associated with the task as healthy cases do. Other than the verbal memory shortfall, the attentional/executive function disorders and processing...
speed decline also appear due to preclinical AD. The aggregation of delayed recall test and executive function examination appeared to have the maximal accuracy in distinquishing preclinical AD [84].

### 2.3.8.3 General Practitioner Assessment of Cognition - GPCOG

GPCOG is the combination of both, cognitive examination of the patient as well as informant interview to upsurge the predictive skill. These parts may be scored sequentially, independently or both together. The first part which is related to cognitive domain consists of nine points: time direction (1) clock sketching (2) drawing numbers from 1 to 12 on as equal spacing as possible (3) drawing clock hands at correct positions, (4) knowledge of a latest news affair and remind an address and name) (5) surname, (6) first name, (7) number, (8) city, and (9) street. Each question holds one point meaning all questions together lead to a highest score of 9. (the less the points the higher the impairment). During the interview six historic queries are questioned by an informant or close relative that knows the patient very well. After that the informant compares the patient’s current function/result with the past years’ performance(s). The parts which are included in the informant interview section are word searching problems, memory problems, problems related to management of finances, troubles in dealing with medication self-sufficiency and need of help with transportation. The whole session of GPCOG requires less than four minutes including informant interview and cognitive test which makes it very quick and brief tool for screening the cognitive impairments [85].

![General Practitioner Assessment of Cognition (GPCOG)](image)

**Figure 16 – GPCOG [86]**

### 2.3.9 Storing neuropsychological test results

The paper based neuropsychological test results are popular to be valuable tool in order to assess one’s cognitive level and presence of any neuropsychological disorder. The next thing after completing the test session with patient is storing the record of test result. No doubt there can be multiple patients being examined by one clininc-neuropsychologist and even single patient can be examined multiple times and these examination results are typically stored or kept in multiple ways. One way to save the test results permanently is the clinicians keep these filled-in test papers attached with
the patient’s medical file which also is paper-based documentation as a record. They even use these paper-based records to assess the patient’s cognitive situation [81].

The second most adopted way to keep the test records permanently safe is to use Hospital Information System (HIS) and Electronic Health Records (EHRs). HIS refers to a digital computerized system through which all the information related to a health care provider/clinic can be managed that allows them to do their jobs conveniently as well as effectively. These systems were first announced and commercially available in 1960s and got developing to advanced versions with the passage of time to modernize the facilities in healthcare environment. The technology was not very advanced at that time and so the computer systems, that’s why updating and providing the real-time information was not so easy and quick as it is today. The clinical staff used to adopt this system just for the sake of hospital/clinic related bills and inventory management but the intentions to use this system have also developed and nowadays the HIS’ primary duties include all financial, administrative and clinical/medical information management. Reliable and quick access to all the related information including patient’s records e.g. age, gender, demographics etc. is now just a one click away after the hospital have switched to modern versions of HIS [94]. Similarly, the pen and paper based neuropsychology test results are manually entered to this HIS for the evaluation of patient’s cognitive domain.

EHRs is a system which focuses on the patient’s health in a broader window by going outside the common collection of clinical data in the care providers’ offices which never goes out of its origin. This system targets a better care for the patients as they are developed in such a way to make this collected information available beyond the clinics/hospitals. They are designed to share the patients’ related data with different health care organizations outside the hospital/clinic for example specialists and laboratories, so that the concerned departments of any organization can fetch any required data anytime without any hustle to better assess the patients. Transforming the results of paper-based neuropsychological tests into electronic health records makes it possible for other clinicians/neuropsychologists to better understand the patients’ history and evaluate the current cognitive situation more concisely [96].

There are several standards to follow for transferring the patients’ clinical data between different software applications used by different care providers. Some of them are Health Level 7 (HL7), Health Informatics Service Architecture (HISA) and Clinical Data Architecture (CDA). HL7 is known to be the most commonly adopted set of standards by clinicians. These guidelines provided by a non-profit organization are developed particularly to use in industry of healthcare. It links different computer systems hosting healthcare specific applications by consuming a typical protocol used for messaging. There are great chances that the systems owned by different clinics/hospitals may have a huge variation in their hardware and software versions or architecture in the aspect of different services which makes it difficult for them to communicate with each other. HL7 addresses this setback and provides a framework through which the hospitals are exchanging, integrating, sharing and retrieving the electronic data of patients’ health. There are different commercial products currently using these HL7 resulted international standards [95].
3. SYSTEM IMPLEMENTATION

3.1 Synopsis

Considering the neuropsychologists’ needs and suggestions, smart device application seemed to be the solution to address the problem of pen and paper based diagnosis tests and manual entry of these test’s results to the server involving extra resources. The software application was required to run on each platform whether its Android, iOS or Windows but for pilot testing and getting neuropsychologist’s insights about it the tool was primarily suggested to build to run on iOS operating system.

The goal is to develop a solution for digital entry of neuropsychology tests results to the server where these results would be visualized to support the clinical decisions later. By using this tool, the clinician can either use the application while examining the patient or after having them examined (submitting data with past date). With the implementation of this tool, there would be no need to take care of data unlike filled paper entry forms as it would safely be saved on server and used to graphically visualization when needed.

3.2 Iterative development of system concept and design

The development of “Neuropsychology Digital entry” iPad application consisted of iterative development process which continued for several months and included two main phases. During first phase, the idea and design of application’s features and navigational model were broken down into small segments and then refined. These segmented ideas and designs helped to achieve a confirmation of key model of the application, the required contents together with the precise features and rules of the solution, and ultimately the classification of the essential objectives and goals of the entire project.

The second phase consisted of implementation of the pre-decided model. It was comprised of numerous steps including literature and documentation reviews related to software development for the iOS platform, creating a basic but appealing and efficient user interface, building the required programming code in order to achieve the minimum viable version of the application. This version was iterated through several phases of application testing and then fixing the bugs and inaccuracies along with the modification of application’s content in order to improve its user experience and functionality.

3.3 Brainstorming and ideation

As earlier described, the application’s concept was formed at the initial stage of the project which involved numerous brainstorming meetings with supervisor, who was also the manager of this project in the organization, with an exclusive intent: to create an idea for an application which should be supported by iOS platform and by using this solution the clinicians examining the Alzheimer disease’ patient will get facilitated. Until the final idea was developed, there were many approaches adopted, assessed and then wiped out. After having many brainstorming sessions and many ideas out of these sessions, a final version of the application was decided to implement and then evaluate its performance before going further into the complexities of additional features. The final approach or model resulted from the initial sessions of ideation, and which was adopted
as the starting point of application development, looked like the following UI wireframes. This interaction model was first in the form of a paper and after finalizing the idea it was then designed in the form of wireframes using the JustInMind software application on Mac machine.

Figure 17 - UI wireframes of application flow
3.3.1 Implementation

For testing purpose and assessment of user experience of minimum viable version of the application, at first the entry form was statically designed in collaboration with the supervisor in the company through an iterative process and experimented by senior solution architects of the organization. This form was just a digital version of the MMSE (Figure 14 - MMSE test form) test form and all the controls were exactly the mapping of this test’s paper version. There were 2 solution architects who were invited to an inhouse evaluation meeting, including 1 software developer and 1 project manager at office, to assess the working experience with touch controls. They operated the application, assessed its features and compared its performance against the traditional pen and papers based tests. After having it evaluated, their feelings were very positive towards the application and a decision of having the feature of dynamic creation of clinical data entry forms was made and then some new screens were idealized, designed and then added into the application which looked like the followings wireframe screenshots.

![Wireframes of screen for designing the test forms](Image)

Now the current version of tool contains this feature of dynamic designing and modifying the already designed forms but this will in future require its users to have authorized roles/access. This feature enables its users to save its designed/modified forms permanently. There can be unlimited number of test forms created by a user which later on can be modified if some change(s) required. Same is the case with patients’ data. The user can create/add new patient and update it any time if required. By selecting any already saved patient or adding new one and one of the entry forms the user can save patient’s clinical data, while in iterative development process the feature of updating patients’ already saved clinical data has been implemented. There is also a set of APIs built to transfer patients’ clinical data from client tablet application to server.
and again make this data available to same client or other applications to use. These APIs and all set of resources used in this project are described below in detail.

### 3.4 Content Model Diagram

A content diagram is a representation of the structure of an application’s user interface. It shows the containers, or screens, of the application and describes their functionality [Stone et al., 2005, pp. 154–161]. Following model diagram (Figure 19 - Smart solution’s content model diagram) describes about all the screens currently present in the application along with their available features, controls used while designing the screen and any possible constraints that can be there related to user rights or data. Constraints here mean needed roles or credentials to operate some or all features of the solution.
3.5 Navigation Model

Navigation model is the flow of application from entry point to the end of processes. Each activity is considered as node and the arrows connecting one activity with other are called links. Navigation model makes it easy to have an overview of what the purposed solution is offering and where or how to access the required feature. The below mentioned figure (figure number) represents each activity/screen and its corresponding next activity/screen along with their main features or tasks. This navigational flow is the final version currently but the solution will be designed in a generic way as if there comes a need to improve or update the flow in future then It should not be a tough job to perform.
3.6 Behavior and Functionality

The complete flow with screenshots and working of iPad application is shown below from signing into the application to submitting the patient clinical data to server.
The first screen of application asks user for its credentials to get into the tool. Currently there is no sign-up option as the credentials would be created from web application. Based on the roles of user credentials the further features of application would be made available to user whether he/she can create/update/delete the data entry forms or not. There is a big logo in top-mid of screen containing application name which was suggested by the organization. The name of application is self-explanatory as it refers to early identification of neuro diseases (ND).
After getting into application, the user can see a list of patients he/she has already saved into the system as shown above (Figure 3). The list is scrollable, making it easy for the user to easily access hundreds of patients’ clinical data at the same time. The order of the list is from old patient to new patient and from top to bottom. Currently, the patient ID, name, date of birth, and gender are shown in the list. At this point, the user can edit or delete any patient. Tapping the edit button of a patient’s data row takes it to the next screen where all the editable fields are already filled in, so the user can edit the patient’s info with minimal work done. The delete button represents the delete patient feature which prompts the confirmation box before the patient is permanently deleted from the database.

Above the patients’ list on the right side, there is an option to create a new patient that will take the user to the next user entry screen (Figure 4) where a new patient can be created as well as new entry tests data can be saved against that patient. On the left side, above the list, there is a welcome message with the user name of the current signed-in user.

The bar button at the top left corner of the screen with the name Logout takes the user out of the application and removes every locally saved user data.
Editing old or creating new patient takes the user to above mentioned (Figure 4) screen. The top portion above black separator line is patient’s personal information which the user can edit and save anytime. While editing or creating new patient no clinical data can be saved against that user as the select test option is disabled.

When the editing or creating a patient is finalized and saved to the system the select test feature is enabled. This “Select test” text box pops up a list of test forms created by the authorized person of user’s own clinic. When selecting one of the test forms list and tapping on “Done” button the user is taken to next screen (Figure 4) when the selected entry form fields are rendered dynamically.

After saving the patient’s clinical date on next screen (Figure 5) the application takes the user back to this screen and the saved entry is shown in the with test name, test date and the option buttons to edit or delete the saved entry. The edit button takes the user other screen (similar to Figure 5) where the entry form is shown in populated phase with the old value that were saved in past. The user can update any or all fields and update them on the server by tapping the update button on bottom right corner.
Selecting one of the clinical entry form from already designed ones’ list the user comes to above mentioned screen (Figure 5) where the corresponding fields are rendered dynamically with specific control types (here all are radio buttons). The top part above black separator line is the patient’s data against which the clinical data would be saved and shown in future.

The date text box on the top right corner below separator line is date of test, by default it will show current date but can be changed if user wants (but not to future). In some cases, there can be no date text box because while designing the entry form user can enable or disable this date feature and by default current date will be saved in database and shown in future.

On the left of date portion, there is test name and below this there are field headings and names. Currently there are six input field types and three input methods that are explained later in this document. This form requires to fill-up all field if not it will prompt an error message as all fields are mandatory to be filled. When the user has input all fields, there is a “Done” button on the bottom right corner to save this clinical data permanently to the server. After submitting this entry form to server, the application takes the user back to Edit/Add New Patient (Figure 3) screen if he/she wants to edit old or save new data regarding current patient.

**Figure 24 - Entry form**
The highlighted button at the top right corner of Edit/Add New Patient screen is the feature that a user with authorized roles would be able to have and use. This button takes the user to next screen where a list of already designed entry forms is shown that can be edited and deleted any time.

Here is the screenshot of editor where a list of two entry forms having edit and delete buttons is shown. There is another bar button at top right corner of screen “Create new”. Here is the feature to create new entry form on next screen and after creating new one the user will be redirected to this screen again and the list of entry form would automatically be updated.
Form designer screen consists of two parts the upper one above black separator line is form metadata while the lower part shows the appearance of entry form how it will look like. The upper portion itself contains two parts, one (Test Name and Date of Entry) for the form as a whole and second (Field Name, Data Type and Input Type) for single field. At the bottom right corner of screen there is “Create test” button that enables after entering the form name and disables if form name field is empty. Then there is a date option if user wants to have a calendar in the form otherwise the date of the day would be saved with data. This option is by default enabled.

![Figure 27 - Test form designer](image)

Below these two field there comes the single field metadata part. There are mainly three different fields/text boxes one for the Field/Entry name that will be shown on left side of row, second is data type of Field/Entry and last one is input type. Currently there are six data types that include Date, Integer, Float, Text Choice, Plain Text and Heading. Based on these data types there are three kinds of input method simple Text box, Radio button/Selector and Scrollable view. These input types are completely or partially available based on the type of data type user selects. In screenshot, there two additional fields can be seen at the right side of Fields name and Data type, these fields collect additional information regarding input type e.g. if user selected Integer data type and Radio Button input type, these fields require user to enter the range of these integer values.

At bottom, right corner of upper portion (form metadata) there is create field button to actually create this field and add in the form. It will add the field into entry form
and show up in lower portion as shown in screenshot. After adding the fields into entry form there appears two option along with field. On the left side two small row buttons appear to move this row up or down in order and on the right side there is a delete button if user wants to delete this field from entry form.

Finally, when user is done entry form design the create form button saves this form permanently on the server for future user and takes the user back to Editor screen where the list of entry forms is updated. As discussed above this entry form list row contains an option for editing the entry form. By tapping on this option, user is taken to the designer view and all the entry form fields are rendered on the lower portion and button “Update Test” appears at the bottom right corner as shown below (Figure 11).

![Figure 28 - Already designed test form](image)

Once the user tapped update test button, it will modify the entry form permanently and there is no option to revert old version or undo the changes.

### 3.7 Technologies and tools

#### 3.7.1 Technologies

The developed system is a client-server architecture in which tablet-tool works as a client. This tablet-tool communicates with the server in order to save/fetch data to/from. This communication is based on Web Representational State Transfer (RESTful) appli-
cation programming interfaces (APIs) which uses JSON formatted data to transfer to and from server. The web APIs are also known as web services. In applications of this modern and complex era, the most vital and required things are interoperability, genericity and reusability of code and it is because of data and platform heterogeneity being headed by growing and rapidly changing IT trends of cloud computing and mobile technologies [7]. For the development of standard-based and loosely coupled software components the principles, strategies and patterns have been introduced by Service-oriented architecture (SOA) [8].

![Service oriented architecture](image)

The basic building block of complex distributed application is considered to be these services which make them and furthermore being made as loosely coupled as possible and increase their scalability.

Enterprises of each level are showing their strong interest towards software-oriented architecture (SOA) as it accelerates the development of software applications and by solving application related issues and decreasing the total cost of ownership it helps to control the business environment of dynamic nature more efficiently [9]. The scalability of this architecture will benefit the future development of android or any other platform based application just like current version, as there will be no need to develop backend from scratch and all the Data access layer (DAL) will already be there in full operational mode. This idea of possible multiple platforms based application made organization think about developing current application in Xamarin environment.
In this client-server architecture, web APIs receive/send data from/to client app and save/fetch it to/from MySQL database on the server hosted on azure cloud by Microsoft. Server architecture follows MVC and entity framework code first approach.

### 3.7.2 Tools specifications

- Application Platform: iOS
- Supported Platforms: iOS 7, iOS 8, iOS 9, iOS 10
- Development Environment: Xamarin
- Development Technology: C#
- Supported Devices: iPad 2, iPad (3rd generation), iPad (4th generation), iPad Air, iPad Air 2
- Development Platform: OS X El Capitan
4. USER STUDY

The study for the evaluation of purposed smart solution was conducted following the qualitative research method. The focus of this research method is to observe the experiences of users in detail by adopting any one or more of the means e.g., in-depth interviews, focus group dialogues, content analysis, observation and visual methods. One of the main distinctive outcome of this method is it makes possible for the researcher to point out the problems from participants’ perspective who took part in study, and understand how they take the meaning and what are their interpretations about events, behavior or objects [11].

Semi-structured interviews with pre-defined list of questions were chosen to conduct this user study. These interviews provided the required research supporting data and evaluation results of smart solution based on real users’ experiences. In the user study, first the recruited users were asked to perform a set of pre-defined tasks using purposed smart solution and after completing all or partial tasks there was a semi-structured interview session. The questions for the interview and the tasks to perform were prepared and printed out beforehand.

4.1 Study Objectives

The main objective of this study was to evaluate the performance and user experience of smart solution. Study aimed to investigate how well this application is serving its purpose in a specific context: the examiner/clinician already knows the number of questions to be targeted and should be added into the test form, they don’t want to use the pen and paper for this anymore and desires to save the test results directly to the server without any manual data submission through some entry form to their health information system (HIS). By compiling these all goals together, the following research questions resulted as the focused areas in a formal way to well address these issues:

1. How can the patient’s examiners be provided a better way to submit collected data to HIS (Health Information System)?
2. How can the work done (by clinicians) be minimized (by using digital application for data entry) to gather information/data while patient is being examined?
3. How can the examiners be enabled to design test forms (soft entry forms) according to their needs and update them whenever they want, without affecting the previously collected data against old version test forms?

Regarding the list of tasks to perform while conducting the user study the following questions were also considered while observing the users’ behavior and expressions against each single action:

1. How do they react and how comfortable they feel when they first see the application and are handed over a list of tasks to perform?
2. How much time they are taking to find desired control to perform some specific action and how easily they are able to use this control?
3. What tasks participants find difficult to perform?

Before and during the test session, the participants were asked to adopt think-aloud method to reveal what they are thinking in their minds specially when they are finding for some control or stuck somewhere.

4.2 Recruitment procedure and participants

The best match user group that should have been recruited for this research study were the AD diagnosis professionals/clinicians but as mentioned in the chapter of “Limitations” it was not possible to sit into the session of neuropsychologist and possible patient where the clinician conducts the AD prediction tests. That is why the users recruited for this study were not very directly the AD professionals but somehow, they were the representing a group of stakeholders of this product as they were developing another system for the diagnosis of Alzheimer and other cognitive impairments.

There were 4 subjects (Table 1) who participated in this research study. The Subjects were recruited from within the organization (Combinostics Oy) by scheduling the appointments through in-house emails. The study included a list of tasks to perform during which the participants were observed that how they interpret the statement of task(s) and then perform it. After performing the tasks, a post-interview session took place and these interviews and tasks sessions were conducted with one participant at a time. All subjects were given a written consent to sign (Appendix A). The information used for the present research study represent a subset of data with demographic information for the huge studies. The 4 in-house subjects were chosen due to limited/no access to actual users of the product in the real atmosphere of Alzheimer patient examination. There were total of 8 tasks to perform one after the other as almost each task was dependent on previous one and total 13 interview questions in which 6 questions were of open-ended interview nature while the other 7 were task specific question.

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender</th>
<th>Specialization</th>
<th>Position</th>
<th>Nationality</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>Male</td>
<td>Ph.D.</td>
<td>CSO at Combinostics Oy.</td>
<td>Finnish</td>
</tr>
<tr>
<td>40</td>
<td>Male</td>
<td>Ph.D.</td>
<td>Senior software engineer at Combinostics Oy.</td>
<td>Finnish</td>
</tr>
</tbody>
</table>
### Table 2 – Characteristics of participants of user study

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender</th>
<th>Education</th>
<th>Profession</th>
<th>Nationality</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td>Male</td>
<td>Ph.D.</td>
<td>Manager image analysis development at Combinotics Oy.</td>
<td>Finnish</td>
</tr>
<tr>
<td>39</td>
<td>Male</td>
<td>MSc electrical engineering (signal processing)</td>
<td>Senior software engineer at Combinotics Oy.</td>
<td>Finnish</td>
</tr>
</tbody>
</table>

### 4.3 Methods and Procedure

As mentioned above there were total of 4 participants took part in the study and each session was conducted with one participant at a time. Each session was held in a silent and comfortable space inside the Combinotics’ meeting area. The participants were sitting on a comfortable chair having a semi-round wooden table in front of them. There were some cookies and a cup of coffee placed on the table for participants. The atmosphere of the sitting area was settled in a laid-back and peaceful way so that the participants may feel calm by forgetting as much as possible that they are participating in a study but examining some real AD patient. These conditions will resemble the actual circumstances where the examination activities would take place, however the participants were also encouraged to act more freely and friendly.

Furthermore, it was ensured to the participants that the feedback gained through their participation will be reported as anonymous users. It was also stated that the only requirement of this study is to act naturally that means no prior experience of clinical/medical tests conducting/designing is required. During the interview session, participants were encouraged to speak out whatever they are thinking in their minds and sincerely express their assessments. It was also stated that even negative viewpoints and disliking feedback would be similarly valuable and welcomed as positive ones. Every session went on for around 45 minutes, of which tasks completion took 20-30 minutes.

#### 4.3.1 Background questionnaire

In the start of every session, a form was given to every participant and were asked to fill in. In addition to giving their personal details (gender, nationality, age etc.), participants were required to provide answers to some background queries about their familiarity with activities relevant to the technology. The inclusion of this form within the user study had 2 purposes:

1. To collect combined data concerning the various participants as a whole, so as to make a general image of those individuals who participated in the study.

2. To retrieve information concerning every participant individually, so as to create some assumptions regarding their individuality which can benefit in the interpretation of their feedback and behavior.
A consent form was also given to the participants in the beginning of each session and were asked to read it carefully and then sign it. The form contained the statements saying that there can be recording of video and possibility of taking pictures of them while participating into the study which can be used in the formation of results and will remain as anonymous data. After reading and signing this consent form they were requested to insert their information into the form covering background related questions. By returning both the filled in and signed forms, participants were handed over an iPad device with the “Neuropsychology Digital Entry” application installed in it as well as the already printed list of tasks to complete and were asked to complete as more as possible number of tasks but try each task at least for once and if they feel unable to complete it they can skip it anytime. During the next and final segment of the session, an interview was conducted in which the contributors were requested to speak out about their opinions regarding this smart solution and other issues about the idea.

In all of the four sessions, the followed practices were quite similar having some minor unarranged alterations and adjustments which were subjected to the situation and are not worth covering or mentioning. In the beginning of each session it started with telling the summary of application’s background and nature to the participants. After this explanation, they were given the iPad Air 2 device and requested to start completing the provided list of tasks. The connection between the application and server was well checked beforehand, and the set of questions and countdown timer was already arranged and set. There were total of eight questions listed in the form and the participants initially had to give answers to all of these. They were also stated that there aren't any wrong or right answers to these questions, and their feedback wouldn't be documented or used beyond the extent of this study session.

4.3.2 List of tasks to perform

The tasks’ list looked like:

1. Login to the application using
   - Username: usman@combinostics.com
   - Password: 123
   and create a patient with following details
   - First name: Nina
   - Last name: Michael
   - Gender: Female
   - Date of birth: 20 March 1982
   - Patient ID: 123456-6543

2. Create a test entry form which should list some or all questions and possible answers to these question of MMSE test (MMSE test’s hard copy was handed over to subject), but if you think the answer can be long enough than you can use the Edit Textbox in place of possible answers list.

3. Edit the previously added patient’s detail and replace its first name with “Mathews” and gender to “Male”.
4. Consider me (researcher) as your patient and conduct your prepared test, you can save my answers to the application.

5. Update the previously designed test entry form by adding or deleting some questions and save it.

6. Update the test results of the test you conduct recently even if you have already updated the design of test entry form.

7. Delete the patient and logout the application.

4.3.3 Interview Session

During interview segment which began after the completion of tasks list, the participants were asked to honestly express their opinion and thoughts regarding the idea of application generally, similarly as their viewpoint on specific aspects and options. Next, they were asked to recall if they’d participated in any similar kind of activities in the past, and to match them with “Neuropsychology Digital Entry”, mentioning benefits and drawbacks of developed solution.

The participants were then encouraged to express their valuable thoughts on how the application may be improved or changed in line with their preferences, either by altering a number of its current features, or by implementing new ones that they might suggest. Finally, the participants were asked to propose the use cases or contexts in which the application containing the characteristics of “Neuropsychology Digital Entry” might be used, and would have a positive impact according to their opinion.

The interview was managed to conduct using an approach which made participants feel comfortable to genuinely express their views, even if they may be criticizing of the application’s idea and the study they are participating in. The questions were addressed to the each of the participant, and all the participants were encouraged to speak and express their thoughts freely, while not being commanded or guided to any specific direction. During this session, there was often a long discussion between interviewer and interviewee in result of additional questions coming out of participants’ answers. The interview segment results have been presented in the next chapter.

4.3.3.1 Post-tasks interview questions

There were two types of interview question asked to the participants after they completed the tasks list handed over to them.

4.3.3.1.1 Tasks specific interview questions

1. How do you rate the first task and why? It is easy to login the system and create new patient. (Where 1 represents disagree and 7 strongly agree).
2. How do you rate the second task and why? It is easy to create a new test form if you are trying to map the questions from hard copy to soft one. (Where 1 represents disagree and 7 strongly agree).

3. How do you rate the third task and why? It is easy to edit the patient details once you have already created the patient. (Where 1 represents disagree and 7 strongly agree).

4. How do you rate the fourth task and why? It is easy to save patient’s test results through application. (Where 1 represents disagree and 7 strongly agree).

5. How do you rate the fifth task and why? It is easy to edit the test entry form once you have already created and saved it. (Where 1 represents disagree and 7 strongly agree).

6. How do you rate the sixth task and why? It is easy to edit patient’s test results once you have already saved the test results to cloud and even updated the test form (in task 5). (Where 1 represents disagree and 7 strongly agree).

7. How do you rate the seventh task and why? It is easy to delete the any patient from the list. (Where 1 represents disagree and 7 strongly agree).

4.3.3.1.2 Open-Ended interview questions

1. What did you think of when you saw the application’s first screen?

2. What did you find good while using the application?

3. Was it easy to find the required buttons/links/controls?

4. Is there any touch control(s) you think was difficult to use or touch?

5. What do you think can be improved in overall application or specifically related to anything?

6. Any general comments related to or not to the proposed solution.

4.4 Devices and tools

- Wi-Fi connected Apple iPad Air 2 device with iOS 10.
- Stopwatch
- Video recording and image capturing camera.
- Voice recorder (if someone does not want to appear in video clip)
- Consent forms
- Background questionnaire forms
- Some pen and pencils.
- Blank white papers to note down any observations made during the test session and answers of interview part. A small set of blank papers with a pen was also given to the participants if they want to write something during the session.
4.5 Summary

A user study was conducted in order to assess the efficiency and productivity effectiveness of smart solution by completing the provided tasks list and also to obtain the valuable opinions and comments regarding its idea. A total of four participants were contacted and asked to take part in this study and all of them agreed to participate after which the time and venue was finalized according to their ease. They were also asked about the food and drinks they would like to have during the study session just to make them feel relaxed and comfortable to answer the interview queries and express their thoughts. All the participants were IT professionals and included regular employees and co-founders of Combinostics Oy company.

During the study sessions, which was approximately 45 minutes long, the participants were given the consent form, asked to read and sign it, addressed about the background of developed solution, requested to complete the tasks then answer the interview questions and at the end they were encouraged to speak out their general views about it. The sessions with all the participants went in line with the planned schedule and arrangement.

The transcript forms and recorded videos captured during each session were utilized to generate conclusions and observations regarding the “Neuropsychology Digital Entry” application, which are examined and explained in the succeeding chapter.
5. STUDY RESULTS

As indicated in the previous chapter, the background questionnaire form, recorded video, and interview notes which were the results of four different sessions of user study, were deeply analyzed to conclude the results carrying the aim of understanding valid outcome regarding how well this solution achieved its purpose of existence. The purpose of concluding the results based on user study is to reveal the fact of how the “Neuropsychology Digital Entry” named smart solution affects the role and efficiency of clinicians while examining the patients in clinical environment. Moreover, the aim of documenting and interpreting the participants’ opinions and comments is to determine how they understand and value the application’s design and concept, as well as what more features can be integrated into the system and what modifications can be made to the existing ones in order to make the product more user friendly and pleasing to adopt.

There were two key approaches adopted to interpret and report the results gained from the studies sessions:

1. Observing the participants’ behavior while completing the tasks: This is related to the participants’ think-aloud attitude against different tasks and their strategies to overcome any difficulties if they face.

2. Asking for the participants’ thoughts and their opinions by having conversation with them in the form of post-tasks interview: The essential things or elements related to the participants’ user experiences and application’s model were reviewed and evaluated. The participants were encouraged to give their valuable feedback regardless of its positive or negative nature.

This chapter starts by reporting the in-application performance of participants in each session. A summary of the user study based on the participants’ results yielded in four different sessions, followed by the interpretation of their noticeable reactions towards presented solution and its concept. Afterwards, covering and describing different observations by analysis of recorded video clips and at the end some valuable feedback which came out of the interview sessions.

5.1 Performance

Here the word performance means the number of tasks completed by the participants with what level of efficiency. The efficiency in this context refers to the ratio of smooth progress (total task time for all 7 tasks) vs mistakes (total number of errors) made while performing the tasks in session. To report these results, following table represents the calculated individual score for every participant, as well as the time that each participant took to complete the list of tasks.

5.1.1 Performance chart

Performance result bar chart has been generated using Microsoft Excel 2017. The time in the chart is mentioned as the number of minutes taken by the participants to perform the required tasks. Mistakes bar represents the number of any minor or major errors.
which participants made while completing these tasks e.g., selecting wrong data type for answering the test question or deleting the patient’s record even if not asked to do so.

Figure 31 - Application performance chart

5.1.2 Interpretation

There was same set of tasks presented to each participant to complete in each session and requested to complete as many as possible of them. All the participants appeared to be relaxed and committed to complete all the required tasks. After signing the consent form and providing the background information, they started completing the tasks right away. Before they were in the middle of first task, they were requested to think aloud while performing their actions or if there are some thoughts coming to their minds. They all followed this instruction and adopted the think aloud behavior most of the time.

While performing the actions required to complete the task(s), the proportion of success as compared to mistakes was fairly good. This may be the reason of clear and simplified task description written on the paper. All the mistakes made by them were not of very disruptive nature. There were different minor errors observed in the test session against each participant except one major mistake that was made by three of them. This mistake was observed in the task number 4 in which after conducting a patient examination session they went back to previous screen without saving the patient’s data to the server and lost all the answers. This made them to complete this task again which took most of the time of their session. One possible reason of this mistake is conceived as the position and appearance of the “Submit” button on screen. It appears as simple as a link button and its color makes it merge with the background image. Other than that, there was no major mistake or difficulty experienced by the participants.
One of the participants was facing a bit difficulty to find the right controls at first attempt and tapped on the wrong control for 4 times but then after discovering that he is going in wrong direction he reverted the wrongly performed action and found the right control in second attempt every time he was making mistake. Except in one case (regarding the task number 4), he did not make any major mistakes. All the participants were successful in completing all the tasks as expected in reasonable amount of time which was 25 minutes on average which caused the early completion of whole study session while the expected time for tasks completion was 30 minutes and all the plan was made according this duration.

5.2 Observations

While the participants were busy in completing the given list of tasks or answering the interview questions, their reactions and performance behavior was being closely observed and noted down on a paper for future result compilation process. Their think aloud attitude, verbally expressed reactions and impressions were also analyzed. The purpose of observing the actions and reactions of participants in each session was to understand their behavior and methods they adopted to deal and overcome any difficulty or unwanted situation they faced at any point.

In the start of each session there was brief introduction of application which they all listened very carefully and at the end of this introduction none of them asked any question or clarification regarding whatsoever. Most of the time of their sitting all participants looked relaxed and no unusual or special reactions were observed in any part of the session. During the first few minutes of each session the participants gave enough time read all of the tasks even before starting the first task and this was the common behavior in all of them. There were different tasks’ statements written on the paper read by different participants twice or sometimes three times to better understand the requirement. Two of the participants were operating the application quite fast that one of them was sometimes making mistakes and selecting the wrong option and then reverting it. The reason behind this maybe they both were already familiar with the iPad device as well as the background, concept and nature of the application being evaluated.

During the interview part of session, the participants appeared calm and very open to the questions and feedback requests. They were replying to the interview question in quite friendly way and giving their own feedback and opinions where they were even not required or asked to do so which was actually good thing in order to get maximum output from the user study.

5.3 Interview and Discussion

This subchapter is reporting and analyzing the outcomes of interview and discussion part of session which was conducted at the end and before the participants were free to go. The reported results are documented in the form of aggregated interpretations regarding application’s design, usability and its success in serving its purpose.
In previous part of the session, as mentioned above, all the participants were successful in completing all the given tasks however the tasks completion time varied. In response to the questions related to difficulty level of tasks, all the participants were having similar answers and opinions with some minor differences. When asked about the first task (logging into the system and creating new patient is an easy job), there was no different answer given by any of them and they strongly agreed with the statement. All of them said that it was quite easy to complete even it was consisted of several steps but very simple ones and the application’s navigation was also according to expectation. Regarding the second task (creating a new test form by copying its content from a paper), 2 of the participants selected the 5 (slightly agree) meaning it was more easy and less difficult. When asked about the reason of saying 5, they said that they selected it because of the amount of work needed to convert paper based test into digital form, and it has nothing to do with the application’s design or efficiency. These both participants took around 15 minutes to complete only second task and their statement was justifying this long time. This reaction may be because they were somehow but not very frequent users of iPad device, but that’s just an assumption based on the behavior of other 2 participants which completed the task in less than 10 minutes and they even strongly agreed with the statement that the task was very easy by selecting the number 7.

For third task (editing the patient details once you have already created the patient is very easy to do), all the participants agreed with the statement by selecting 7 (strongly agree) saying it was very easy to update the patient’s personal details after you have created it. One of them mentioned that “Edit” button shown along with the patient’s record on “Patients’ list” screen made the way very clear to update its details on “Edit patient” screen. Coming to the fourth task (saving patient’s test results through application), there were 2 of the participants who completed this task twice in a session as they went back to the previous screen without saving the patient’s test results. According to them, they did it because the “Save” results button was not that clear to them and they thought there is some auto-save feature has been implemented on this screen which will automatically save the test results to server. After facing this problem there were two things or changes that came out of the discussion, one is to implement an alert box asking for the confirmation if user really wants to quit this screen without saving test results, secondly the color scheme or appearance of this along with other buttons should be modified which will make it more apparent and accessible, currently it was getting merged with the background image due their similar color, size of button and maybe its position as well.

The fifth task (modifying the test forms after creating and saving them on the server) also got similar kind of feedback as of third task (modifying patient’s personal details) by one participant. He mentioned the same comments here e.g., improve the appearance of “Update” form button as well as implement some sort of confirmation alert box which can prevent user from losing the updates made on this screen. Moreover, he also appreciated the feature of rearranging the list of questions saying it makes the user freer and empowered while creating or deleting any part of the form. The other 3 participants rated it with 6 meaning the task was very easy to accomplish. In response to the sixth task-specific interview question, each participant was appreciating the way adopted to enable users to update patients’ test results even after updating the format or design of original test form against which this test was conducted. They all strongly agreed with the statement that it was very easy and accessible to edit any test results. While answering the question about the difficulty level of seventh task, none of them...
found it difficult as well but 3 of the participants suggested to implement a confirmation alert box so that if a user mistakenly taps on delete button the patient should not be deleted right away but a confirmation pop-up should appear with some warning message stating that the action is not undoable.

Participants’ overall opinion regarding the developed solution’s concept and its usage was positive and most of their remarks were appreciating and encouraging. They expressed their satisfactory reactions towards the application with the anticipation of its success in achieving the targeted purposes that it will make clinicians feel more empowered while creating different kind of test forms as well as saving their patients’ test result directly to the server without engaging any third person for manual data entry process. The participants were already knowing the background of Alzheimer disease and its commonly known diagnosis tools and techniques available in the market and they highly recommended this solution for clinicians due to its short learning curve as well as popularity of iOS operating system which is highly in demand and easily available with Apple devices.

There were some minor changes or features suggested by some of them which can improve its demand in the market e.g., InApp registration feature with some company provided identity code, switching between multiple clinicians’ accounts working under the same clinic, enabling clinics to have their own organization logo on the top of each or home screen etc.

In response to the interview questions related to the devices which were targeted while developing the application, the interviewees said that they already have quite much familiarity with iPad and iPad Air devices and their old and new operating systems. Some of them having been using this sort of devices since years and playing games as well as using social applications on it. They said they have not used or cannot remember any utility application developed to dynamically design and then use any kind of data entry forms. One of them additionally mentioned that the way adopted to create the input controls then enabling the user to edit it, while designing the entry form, is unique and self-explanatory for the people using it for the first time which makes the user feel already familiar with the app. Some also suggested to rethink about the colors of navigation and operational buttons as they are of blue color and so the background, this color scheme makes them merge with each other and can even be problematic to identify these buttons to click for the old people or the ones having color blindness.

While answering the question related to their initial feelings and thoughts about the application when they saw the application for first time in the start of session, most of them responded that on the first screen which is also the login screen, big company logo having brain image in it made us feel like using some IQ assessing or mind related tasks evaluating sort of application, which was not directly but somehow related to the application’s and organization’s nature. Moreover, they gave positive feedback regarding the flow and design of the application, listing of data as well as the effectiveness and efficiency of the solution with some minor modification which are already mentioned above.

When asked for the specific good things they found while operating the application one of them liked to comment on feature of updating the design and controls of entry form even after collecting the test result of patients against this form, because the
user can add more question or delete any of the already listed ones without effecting the old results. Other participants also appreciated many major and minor things related to design and ideas adopted to covert pen and paper based tests into digital form e.g., using number based radio button for quick input, enabling users to edit the patient’s test results and date at any time in future and showing/hiding total and category based subtotal test scores right after updating any question’s answer in the list even before completing the whole test or clicking the “Save” results button. As mentioned above there were also some minor modifications suggested by the participants and in response to the question related to the controls/buttons everyone suggested to change the look and feel of them as it will make them look more emerged and easy to identify. They also gave the suggestion increase their size at some places e.g., update test button on form editing screen, save results button on patient test scores screen etc.

When they were asked regarding their general comments or opinions about the application or anything in overall session, two of the participants came up with the same suggestion to implement the feature of enabling users to switch between the landscape and portrait orientation mode any time regardless of the screen they are viewing, currently the app is only portrait orientation supported. It was very interesting to get similar suggestion from two different participants in different sessions and this thing made this point valuable and next to-do functionality to implement.
6. DISCUSSION

Information technology is one of the most rapidly evolving field of current era and it comes to tremendous advancement when discussing about the ubiquity of smart handheld devices e.g., cell phones, tablets and phablets etc. There are thousands of mobile applications being developed in one single day supporting different operating systems used by different mobile device vendors. These applications also include health and medical related support systems. The health care professionals (HCPs) are making use of these already available or custom-built smart applications which help them monitor several aspects of their patient's health as mentioned in chapter 2. Medical applications are helping in the diagnosis of numerous health conditions by making all the essential measurements and allowing the access to calculated test results far quicker than several traditional diagnosis tools. This is not wrong to say that these smart devices would surely play a vital role in coming age of medical industry.

This evolving wave of information technology is also surrounding the field of neuropsychology. Before that there have been many traditional ways to diagnose any brain related illness, but these methods were both expensive as well as time taking. There are many diagnosis batteries, in simple words computer based cognitive assessment applications/tools, being developed in the domain of research and then market. These assessment tools are easy to operate, cheap and becoming very popular as they have turned out to be a significant part of neuropsychologists’ diagnosis procedures. Chapter 2 explains all the standard clinical and trendy non-clinical diagnosis methods being adopted now-a-days in the diagnosis of Alzheimer disease or other kinds of dementia syndrome.

By accepting the necessity of mobile devices in the world of health care, this project was started aiming to develop a smart application with the name “Neuropsychology Digital Entry” to facilitate the clinicians in the field of neuropsychology diagnosis tests. The implementation of this project has been thoroughly reported in chapter 3. There was a number of research questions which needed to be focused on and answered while designing, implementing and evaluating the required features. After the development and partial quality assurance phases of minimum viable product (MVP), there was needed a user study to get user insights in order to assess the efficiency and effectiveness of developed solution. Chapter 4 mentioned the whole procedure regarding the recruitment of participants for the evaluation study. Chapter 1 and 4 also discuss the limitation of access to the real users of this product.

There were total of 4 participants who took part in this study. They were required to complete a list of tasks and then answer some interview questions and express their feelings and suggestions to improve the lacking features in application if there are any. They were encouraged to think aloud while performing the tasks and play their role in the improvement of user experience by giving tasks specific opinions at the end of the session. Their whole session, from signing the consent form to interview and discussion part, was recorded either in the form of video or audio clips. These recorded materials and in-session written notes were later used to conclude the study results as well as evaluate the extent to which research questions were targeted.
6.1 Reliability and validity

6.1.1 Reliability

The time when user study results have been concluded by carefully analyzing all the materials and outcomes obtained from the participants’ contribution, now is to estimate its reliability and validity in order to make these results valuable. The reliability of any research refers to the extent to which the same user study provides consistent results even if some other group of researchers perform it or same researcher performs it with other group of participants.

The reliability of a user study can be measured by discussing different factors and some of them can be referred as participant error, participant bias and researcher error etc. Starting from the first factor, which is participant error, refers to some condition or situation which leads the participant to make some error while performing the required tasks or answering the interview questions and this error can make this study results unreliable. This condition or situation can be related to anything e.g., day of the week, time of the day or health condition of the participant etc. To avoid any of these unwanted situations, the recruitment of the participants was done through an email in which they were asked to select any day of the week and any time of the day so that they can participate according to their ease and availability of time. Before starting the interview session, they once again were asked if they are feeling good about the session and can leave the session at any time even without telling the reason. All the participants selected the days and time according to their comfort and participated in a pleasant mood. So, the results of this user study can be considered as reliable as could be possible considering the first mentioned factor of reliability.

Participant’s biased behavior refers to the environment or background in which he or she answers to the interview questions or a questionnaire in a deceitful or insincere way. Biased response can also be the result of unclear or ambiguous statement of the questions which can be difficult to understand or convey the false meaning. This biased attitude makes the study results unreliable and confusing. To prevent this kind of situation or environment, this study was planned in as similar to the real Alzheimer examination environment as possible. Referring to the statements of the interview questions, all the statements were written using simple and straightforward language. These interview questions and tasks’ statements were also reviewed and approved by the supervisor. The sessions were conducted in a silent as well as pleasant environment. This study also did not require any prior experience of using any similar kind of application or background knowledge related to anything. Before starting the test session, participants were also asked if they are feeling comfortable or need anything to make themselves feel relaxed.

In addition to the relaxing and silent environment, they were also encouraged to criticize any sort of deficiencies they may find while using system, so that they can feel more liberty and privileged while judging the application’s efficiency and performance. They all were offered a cup of coffee with some cookies and treated as valuable guests to make the atmosphere more respectful and friendly at the same time. Taking the above-mentioned aspects into account, the reliability of study results reported in this
thesis can be considered of high value as there was apparently no response bias behavior of any of the 4 participants.

Discussing the factors of researcher error in reliability refers to the wrong interpretation of study results or alterations to participants’ feedback. This kind of errors may ruin the reliability of any study no matter how well it was planned and conducted. One of the major reasons which can lead to this error is trying to get more than usual outcomes in shorter period of time to hastily complete the study and finalize the results. One situation can be conducting all users’ sessions, which can be 4, 6 or even 8, in one single day. Another reason may be asking too many questions from a single participant in an interview or questionnaire that he or she starts feeling irritated about it and give confusing or ambiguous replies to these questions.

In order to avoid any such researcher error, all the 4 study session were conducted one after the other and not any two on the same day. As discussed earlier, the participants were sent an email, with a request to participate in the evaluation session of the application, providing a pre-defined list of days and time slots so they can select the day and time according to their ease. If one of the participants had already selected a day from the list, no other participant could select the same day in same week just to emphasize on one participant in a day and carefully manage the outcomes of its session. The questions asked during the interview session were also very relevant and not too many that could disturb the participant. All the 4 participants were giving an open and sufficient feedback in response to the last interview question which shows that they were not getting annoyed even after asking 13 questions and still available for more discussion if needed.

6.1.2 Validity

Validity of a research refers to the extent to which the study was successful in measuring the aimed results. In this project, the purpose of the user study was to evaluate the usability of an iPad application developed to facilitate the clinicians. For this objective, 4 user study sessions were planned and conducted with one participant at a time, in which they were required to complete a list of tasks and then answer some question in the post-tasks interview part. The tasks of the session were carefully prepared so that each and every feature of the application can get evaluated. After making this tasks list, a meeting with the supervisor was arranged to improve the questions’ statements as well as adding more task if some feature appears to be missing from the list. Referring to the research questions of this thesis, all the required aspects of solution got evaluated with these sessions. The validity of the results became more valuable due to diverged backgrounds of the participants which revealed the actual usability results of the system.

The interview and discussion part of the session covered the targeted characteristics of the application more clearly and precisely in which the efficiency and effectiveness of the system was deeply analyzed against the feedback of the participants. In response to one of the questions asking for their general views and opinions regarding the application, participants provided a detailed and issue specific feedback that covered all the missing concerns, if there were any, which can be implemented to make the product more convenient and user friendly.
6.2 Design and implementation reflections

Considering the research questions of this project, the first one refers to facilitating the clinicians with an improved and digital way of collecting patients’ test results without using any pen and papers, so that the data can directly be submitted or uploaded to their hospitals information system. In achieving this goal, the system was working and providing the results as expected. In this system, iPad application was playing the role of client which uses web APIs to connect with the server application built on .Net Core technology and hosted on Microsoft Azure cloud.

The second question was to minimize the required number of taps/inputs to fill in any kind of test forms and upload the recorded results to server while keeping the interfaces as simple as possible at the same time. This requirement was always kept in consideration during the designing phase of the application though many custom-built user-controls were also used while building the interface, which minimized the number of taps/inputs to considerable extent. For the purpose of reducing cognitive overload and user interference in designing and editing the test forms, patient details and other stuff, there were some suggestion-boxes and pre-filled input fields also used to aid the user input.

It was also required to enable clinicians to dynamically design any kind of test form which can be modified later. Another condition was to persist patients’ test results even if the test form, against which the patient was examined, is modified at any time after the examination session. To achieve these features, the test forms were first converted from rendered controls to JavaScript Object Notation (json) and then saved in the form of plain string into server’s database, along with the patient’s test results, in the same table for patients. While to retrieve these test forms, the plain string was converted back to json and then rendered on the screen according to the notations.

The development of the application was first started using objective-C technology supported by the iOS platform only, but later the decision was made to use some cross-platform development tools and technologies so that the android and possibly windows versions of the application can also be made available in the market with minimum work required. After careful consideration, Xamarin platform (powered by Microsoft) was selected which supports C# as the development language and can generate various kinds of executable archived files to run the application on different operating systems. This was also the requirement mentioned in fourth and last research question.

6.3 Analysis of the results

The conducted user study provided many useful results for the assessment of application’s performance in real environment. The participants who took part in this study were having different backgrounds and only 1 out of 4 was frequent user of iPad devices while none of them had ever used any application like this, but still they were successful in completing all the given tasks within the reasonable amount of time. This result makes it clear that the system is designed and implemented with the satisfactory level of user convenience having shorter curve for learning and getting expert in using its features. The interview and discussion part of the session resulted in many useful
insights from the participants, in which they pointed out different positive and negative aspects found while using the application.

Overcoming the limitations, which are already discussed above, may slightly change the analysis results but not very different from concluded. The output from the interview and discussion part based on the participants’ feedback, even the negative ones, supported the aim that the developed product can be labelled as an effective and valuable addition in the field of neuropsychology tests which can change the nature of diagnosis methods as well as the working and decision making behavior of clinicians.
7. CONCLUSION AND FUTURE WORK

The application developed for the convenience of clinicians in the field of neuropsychology tests is acknowledged to be the valuable solution over the results of usability evaluation study. This application is developed targeting iOS platform used in Apple Inc. offered devices and designed only for bigger screens meaning iPad and iPad Air devices. Using this application, the clinicians can dynamically design neuropsychology test forms before patient’s test session without having any extra-ordinary prior knowledge of smart devices. They would also be able to use this application while examining the patients, they can select and modify any of the pre-defined test forms and save user’s test results directly to the application’s server to analyze them for future decision making purposes.

Concluding the results of conducted study, the “Neuropsychology Digital Entry” can be considered a helpful application which serves its purposes with satisfactory level of efficiency and effectiveness. The limitation of this project is restricted or no access to the clinicians while examining the patients in clinics, which is also the context of use for this application. This limitation became reason to recruit the participants from within the organization, for which this project was developed, to conduct user study and evaluate the designed solution alongside the research statements of this thesis.

This application is developed as the pilot version having core features to demo its performance as well as get feedback from the users. In addition to the current features and after getting feedback from the participants of this user study, there are some modification and new set of features that will be required in next version. The modifications include some changes in the design which can reduce the possibility of number of errors while saving the test results to the server, and implementing a number of confirmation boxes before leaving the current screen if user already have input some data to its fields. The future work required for this solution which can be considered as major updates to the application include the landscape orientation support for the ease of it use, currently only portrait orientation is supported, which will require to once again get through the phases of ideation, design and implementation process so that new user interfaces can be prepared which should look as similar as possible while switching from portrait to landscape orientation and vice versa. The other new feature can be the integration of data representation module in the application through which the clinicians would be able to assess the performance of the patient, comparing the current and all the previous test scores, rather than going to the server portal, search for the patient and then see the results.
8. REFERENCES


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Appendix A: Tasks to perform

1. Login to the application using
   a. Username: usman@combinostics.com
   b. Password: 123
   c. and create a patient with following details
   d. First name: Nina
   e. Last name: Michael
   f. Gender: Female
   g. Date of birth: 20 March 1982
   h. Patient ID: 123456-6543

2. Create a test entry form which should list some or all questions and possible answers to these question of MMSE test (MMSE test’s hard copy was handed over to subject), but if you think the answer can be long enough than you can use the Edit Textbox in place of possible answers list.

3. Edit the previously added patient’s detail and replace its first name with “Mathews” and gender to “Male”.

4. Consider me (researcher) as your patient and conduct your prepared test, you can save my answers to the application.

5. Update the previously designed test entry form by adding or deleting some questions and save it.

6. Update the test results of the test you conduct recently even if you have already updated the design of test entry form.

7. Delete the patient and logout the application.
Appendix B: Interview questions

1. How do you rate the first task and why? It is easy to login the system and create new patient. (Where 1 represents disagree and 7 strongly agree).

   Rating: [ 1 , 2 , 3 , 4 , 5 , 6 , 7 ]
   Reason(s):

2. How do you rate the second task and why? It is easy to create a new test form if you are trying to map the questions from hard copy to soft one. (Where 1 represents disagree and 7 strongly agree).

   Rating: [ 1 , 2 , 3 , 4 , 5 , 6 , 7 ]
   Reason(s):

3. How do you rate the third task and why? It is easy to edit the patient details once you have already created the patient. (Where 1 represents disagree and 7 strongly agree).

   Rating: [ 1 , 2 , 3 , 4 , 5 , 6 , 7 ]
   Reason(s):

4. How do you rate the fourth task and why? It is easy to save patient’s test results through application. (Where 1 represents disagree and 7 strongly agree).

   Rating: [ 1 , 2 , 3 , 4 , 5 , 6 , 7 ]
   Reason(s):

5. How do you rate the fifth task and why? It is easy to edit the test entry form once you have already created and saved it. (Where 1 represents disagree and 7 strongly agree).
6. How do you rate the sixth task and why? It is easy to edit patient’s test results once you have already saved the test results to cloud and even updated the test form (in task 5). (Where 1 represents disagree and 7 strongly agree).

Rating: [1, 2, 3, 4, 5, 6, 7]
Reason(s):

7. How do you rate the seventh task and why? It is easy to delete any patient from the list. (Where 1 represents disagree and 7 strongly agree).

Rating: [1, 2, 3, 4, 5, 6, 7]
Reason(s):

8. What did you think of when you saw the application’s first screen?
Answer:

9. What did you find good while using the application?
Answer:

10. Was it easy to find the required buttons/links/controls?
Answer:
11. Is there any touch control(s) you think was difficult to use or touch?
Answer:

12. What do you think can be improved in overall application or specifically related to anything?
Answer:

13. Any general comments related or not to the proposed solution.
Answer:
Appendix C: Consent form

CONSENT TO RECORD AN EVALUATION TEST

I ask you to participate in a usability test that is part of a thesis project under the Master’s degree from Tampere University of Technology. By participating in the usability test you will help us to evaluate the smart application developed for the convenience of neuropsychologists.

You will be asked to perform different tasks using the service and to think aloud while doing these tasks. In addition, you will need to fill in a background questionnaire. After completing the tasks there will be an interview session in which you will provide your feedback regarding the application or anything in general.

During the test, a video camera will be recording this whole session, its events and audio. The materials recorded during the test will be used to evaluate the usability of the service and then report them into the thesis. It is also clarified that this video, audio or any kind of personal information will only be analysed and used by the interviewer and no one else, meaning while reporting the results you will be mentioned as an anonymous participant and after reporting the results this all personal material will be destroyed.

Please select anyone of the followings.

- I do not want my video to be recorded, only voice is fine.
- Recording my video and voice, both are fine.

You can stop participating and leave the session at any point.
I am happy to answer, if you have any questions.

By signing this form, you will accept the above terms.

Date and place: _________________________________________

Signature: _________________________________________

Name clarification: _________________________________________

For the use of test conductor.
Appendix D: Background questionnaire

Name: __________________________

Age: __________________________

Gender: __________________________

Nationality: __________________________

Education: __________________________

Profession: __________________________

Do you own an iPad or tablet device? If yes, how long have you owned it?

How often do you use iPad/Tablet for any purpose?

Have you ever used any software application which is somehow related to health and particularly brain health? If yes, what kind of?

Have you ever used any software application in which you could design or modify any data entry form as per your needs?