An investigation into engagement processes for user requirements development for a personal healthcare record aimed at health self-management.

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Submitted for the award of PhD

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Glossary

CMOc: Context. Mechanism, Outcome Configurations

DoH: Department of Health

EPA: Enduring Power of Attorney

EPR: Electronic Patient Record a computer system designed to support clinicians by providing accessibility to complete and accurate patient data often associated with one acute service or organisation

EHR: Electronic Health Record in its basic generic form is a repository of information regarding the health status of a subject of care, in a computable form.

eHealth systems: Utilise modern technologies and information systems to organize and integrate the delivery of healthcare.

HCD: Human Centered Design

HCP: Healthcare Professional

HTML: Hyper Text Markup Language. Is the standard markup language used to create web pages.

In-MINDD: The Innovative, Midlife Intervention for Dementia Deterrence.

In-MINDD Tool: The on-line profiler collects personalised demographic, lifestyle and clinical information. The individual receives information in the form of a personalised Lifestyle for Brain Health (LIBRA) score and profile provided through the Support Environment.

Interoperability: The ability of two or more systems to exchange information ISO/TR (2005)

ICT: Information Computer Technology

IHI: Individual Health Identifiers

ISO: The International Organization for Standardization

Localization: (aka "l10n") is the process of adapting a product or service to a particular language, culture, and desired local "look-and-feel".

LIBRA: Lifestyle for Brain Health score received following completion of the In-MINDD profiler.

mHealth: Mobile Health is any medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices

MOBEL: Mobile Electronic Patient Record

MU: Meaningful Use

MySQL: An open-source relational database management system

NHS: National Health Service UK

NPfIT: National Programme for Information Technology in the NHS

NPT: Normalization Process Theory identifies a number of social factors needed for successful implementation and integration of interventions into routine work (normalisation).

Open Source: Open source software is software whose source code is available for modification or enhancement by anyone.

PHR: Personal Health Record

PPI: Public Patient Involvement

VA: United States Department of Veterans Affairs

Support Environment: gives individuals information on their identified dementia risk factors, outlines the national recommendations in their relevant country and supports goal setting to change behaviour.

SHa1: Secure Hash Algorithm

UX: User Experience

URS: The User Requirements Specification.

UML: Unified Modelling Language

WHO: World Health Organisation

Abstract: An investigation into engagement processes for user requirements development for a personal healthcare record aimed at health self-management.

Kevin Power

This study presents an investigation into the user requirements development process for the co-design between stakeholders of a personal healthcare record aimed at self-management of cognitive health. A case study methodology was used to investigate the co-design of the Innovative, Midlife Intervention for Dementia Deterrence (In-MINDD) tool which seeks to address cognitive health promotion in primary community health care systems.

The purpose of this case study was to investigate clinical engagement processes as part of the user requirements elicitation process for a personal healthcare record aimed at health self-management. Interviews, focus groups and usability testing were conducted with identified key stakeholders including General Practitioners (GPs) and service users. The Normalization Process Theory (NPT) framework was employed for its focus on engagement to guide the research design and data analysis.

The case study methodology and NPT process were found to be complimentary approaches in defining user requirements. User requirements were fit for purpose and aligned well to user experience specifications. Results indicated a greater demand for this type of intervention among potential service users as opposed to GPs. The most appropriate way to offer the In-MINDD tool is as a web based Personal Health Record updated by service users. The support environment was identified as lacking sufficient interactivity needing more personalisation and greater service user interaction. Future iterations of the In-MINDD tool should use a combination of personalized feedback and incorporate smart mobile technology to deliver feedback thus better supporting personal wellbeing. This study presents a novel contribution to the field of requirements development research by investigating the role of engagement processes to specifying user requirements for health software. The NPT framework has been applied in a new context and from an earlier stage then previously used. This research indicates that the NPT framework is shown to have further merit applied to user requirements development research.

Chapter 1: Introduction

1.1: **Overview**

There is strong evidence that addressing lifestyle factors in mid-life can improve the chances of avoiding or delaying the onset of dementia. Global trends indicate populations are living longer with a significant rise in chronic diseases. Initiatives that promote addressing lifestyle factors in mid-life are now considered a priority to address the burden of chronic disease and preventable illness. The World Health Organization [WHO], 2015) has called for a paradigm shift in the way health services are funded, managed and delivered. Dementia is on the increase and a proactive approach using early intervention is recommended in Irish policy documents (Department of Health [DoH], 2014) and internationally from the WHO (2012). Some priority actions from the Irish National Dementia Strategy (DoH, 2014) include promoting better public awareness and understanding of dementia by targeting populations that are at risk. Early interventions on modifiable risk and protective factors associated with dementia can help. Modifiable and manageable risk and protective factors associated with dementia include; hypertension, cholesterol, obesity, alcohol consumption, smoking, physical activity, cognitive activity, chronic kidney disease, coronary heart disease and diabetes (Deckers et al., 2015). Strategies that promote primary care service user engagement together in partnership with primary care practitioners are called for. The Patient and Public Involvement (PPI) agenda encourages patient involvement and proactive participation at the earliest stages of research (Irish Society for Quality and Safety in Healthcare, 2009). A key policy agenda from the national dementia strategy (DoH, 2014) is to improve mid-life lifestyle factors impacting on brain health. A need to develop supportive, socially driven online environments to help patients follow their personal health strategy is required. Many eHealth interventions are preventative rather than prescriptive with the aim of empowering service users to engage in self-care management of many aspects of their own health (Hutchesson et al., 2015). This self-care management of health facilitated by a Personal Health Record (PHR) provides the focus of this study investigated using a case study methodology.

This thesis set out to investigate the following research question:

What are the current user and non-functional requirements in regard to self-care management and prevention strategies in relation to dementia risk and protective factors?

To that end the research aims can be described as follows:

1. To gain a deeper understanding of the context into which the In-MINDD tool will be implemented and to illustrate this context to key stakeholders engaged with the process of In-MINDD tool design and development.
2. To understand the conditions facilitating the development of user requirements needed to build a personal healthcare record namely the In-MINDD tool from the perspective of two roles namely (a) the healthcare professional and (b) the service user.
3. To explore clinical engagement processes with stakeholders used to elicit requirements.
4. To investigate the most appropriate way to optimise clinical engagement processes with GPs and service users.
5. To optimise the social and technical "fit" between the In-MINDD tool and the existing primary healthcare domain for sustainable impact.

The first three chapters of the thesis provide an overarching background to the study. Chapter 1 gives an overview of the problem area. Chapter 2 describes literature in the area related to eHealth. Chapter 3 describes literature in the area of requirements development process for eHealth initiatives and introduces frameworks that can be used to enhance potential for optimal deployment and integration with service users and GP services. Chapter 4 investigates methodological approaches outlining key decisions on methodological and design approaches adopted. Chapter 5 describes the research design used. Chapter 6, 7 & 8 present the case study findings in the form of a case study report. Chapter 9 provides an overall discussion and concludes the thesis reflecting on new

insights in regard to user requirement analysis for self-care management of dementia risk factors and health promotion initiatives.

1.2: **Background**

According to the WHO (2012) the world's population is ageing. Ageing trends have led to an increase in the number of people with dementia. Dementia mainly affects older people; however it is not a normal part of ageing and up to half of dementia risk factors can be attributed to lifestyle (Barnes & Yaffe, 2011; de Bruijn & Ikram, 2014; Deckers, et al., 2015; Plassman, Williams Jr, Burke, Holsinger & Benjamin, 2010; Prince, Albanese, Guerchet & Prina, 2014). Dementia is an age related cognitive disease caused by a variety of brain illnesses that affect memory, thinking, behaviour and ability to perform everyday tasks (The Alzheimer's Society of Ireland, 2007). The accelerating rates of dementia are cause for immediate action. With the rising prevalence of dementia worldwide, there is an urgent need to identify opportunities for prevention. In an attempt to contain costs, policy has been to push care into primary care where it is most simple and cost effective (DoH, 2014).

In Ireland GPs are under considerable financial and professional pressures. The free GP care for under 6s scheme introduced under The Health (General Practitioners Service) Act 2014 as part of a wider review of the government's universal healthcare plan has according to chartered certified accountancy firm LHM Casey McGrath (2015) been faced with opposition from the National Organisation of General Practitioners. Many GPs have signed up to this scheme yet GPs are facing increased numbers of consultations, time spent with service users and waiting times (Hennessey, 2015) due to this scheme. The Casey-McGrath report describes a GP sector that is insecure typified by practice closures and emigration of GPs. The National Recovery Plan (Government of Ireland, 2009) has increased demand for a transformation of public health services to meet EU agendas.

Healthcare is increasingly being offered with an aim to reduce or delay the onset of diseases such as dementia in the population as a whole. An increasing body of evidence

has highlighted the role for modifiable risk factors which exacerbate, or reduce, one's risk of developing dementia in later life (Barnes & Yaffe, 2011; de Bruijn & Ikram, 2014; Deckers, et al., 2015: Plassman, Williams Jr, Burke, Holsinger, Benjamin, 2010; Prince, Albanese, Guerchet, Prina, 2014). Good quality evidence exists to identify the following as exacerbating risk: depression, type 2 diabetes, smoking, midlife hypertension, midlife obesity, physical inactivity, and low educational attainment, diet and decreased cognitive activity. Dementia related risk factors that develop in mid-life, such as hypertension and obesity, coupled with the contribution of smoking and physical inactivity, indicate that approaches are required which target populations well before the onset of dementia, while still in the 40s and 50s (Barnes & Yaffe, 2011; Prince, Albanese, Guerchet & Prina, 2014; Norton, Matthews, Barnes, Yaffe, & Brayne, 2014). Taking this into account the focus of this study is an intervention aimed at people in mid-life aged 40 to 60 years.

For the purpose of clarity I will define some important key terms; the In-MINDD concept, the In-MINDD tool and the In-MINDD feasibility study.

1.2.1 The In-MINDD Concept

The Innovative, Midlife Intervention for Dementia Deterrence (In-MINDD) system is a European Union funded project, seeking to address cognitive health promotion in primary community health care systems. Put simply, In-MINDD is a health promotion initiative for early screening of dementia risk factors which produces a service user centred plan which may help to reduce future risk of dementia. In-MINDD developed a dementia risk assessment and reduction system entitled the In-MINDD profiler. The on-line profiler collects personalised demographic, lifestyle and clinical information. This results in service users receiving information in the form of a personalised Lifestyle for Brain Health (LIBRA) score and profile. An on-line support environment gives service users information on their identified risk factors, outlines the national recommendations in their relevant country and supports goal setting to change behaviour. Key principles underpinning this study include a need to develop supportive, socially driven online

environments to help service users follow their personal health strategy. An overarching aim of the research was to raise awareness of the modifiable risk factors for dementia among the target population. A key message underpinning the In-MINDD concept was that there are steps that individuals can take in mid-life to mitigate their potential risk of developing dementia in later life. This, however, means identifying effective ways of supporting individuals to make and maintain changes in health-related behaviors. This is known to be a challenging task. Utilizing the internet as a social support, In-MINDD sought to test the provision of information on dementia risk coupled with access to an online support environment with service users in four European primary care systems. This model was then tested for feasibility through a Randomised Control Trial.

1.2.2 The In-MINDD Tool

This research is concerned with the development of user and non-functional requirements for the In-MINDD online profiler and support environment. Throughout this thesis the In-MINDD profiler and support environment will be referred to as the In-MINDD tool.

1.2.3 The In-MINDD Feasibility Study

In-MINDD was developed by Universities in four partner countries The Netherlands, Scotland, Ireland and France. University of Maastricht (MU) in The Netherlands was responsible for the development of the dementia-risk algorithm. Dublin City University (DCU) was responsible for the IT Development and co-design of the In-MINDD Online Profiler and Support Environment. The In-MINDD feasibility study is currently testing the effectiveness of this approach through a randomised controlled trial (RCT) in Ireland, UK, France and the Netherlands. As part of the RCT (registered with the ISRCTN No 98553005, http://www.isrctn.com/), the programme team conducted qualitative interviews with participants, GPs and practice nurses to explore their use of the LIBRA score and profile and, importantly their awareness and understanding of modifiable risk factors for dementia. Co-design interviews were conducted in all partner countries but this research is concerned with the co-design work carried out in Ireland.

1.2.4 <u>Focus of this Case Study</u>

This case study addressed the issues of technology integration and implementation of the In-MINDD tool into primary health care practice. The PhD research focused initially on gathering requirements for the In-MINDD tool so that it could complement the existing technology systems and achieve optimal clinical engagement. The researcher contacted GPs, stakeholders and service users to aid in the co-design. GPs were interviewed to gain feedback on the look and feel of the In-MINDD tool and to investigate opinions on dementia risk analysis and reduction strategies. Service user focus groups provided the researcher with an understanding of service user perspectives on the design of the In-MINDD tool. The case study findings aided the design of the In-MINDD tool and the process of service user registration. In order to review literature in this area it was important to investigate eHealth systems integration.

1.2.5 <u>Justification for the research</u>

eHealth systems are notoriously difficult to implement and integrate. Sheikh et al. (2011) argue that the potential of eHealth applications for aiding professionals in the delivery of healthcare and service users in self-care management is accompanied by considerable new risks to service users. The Department of Health UK (2014) describe Self-Care Management as the way in which individuals take actions themselves to maintain both physical and mental health, in addition to meeting social and psychological needs. As potentially useful eHealth interventions are developed and deployed, they frequently fail to live up to their anticipated benefits when implemented in practice. Sheikh et al. argue that a major factor contributing to this inconsistency is poor integration with existing work patterns. Early research by Sørby, Melby, & Seland (2005) posit that a well-designed eHealth system should be intuitive, effective, and flexible enough to meet the specific information and communication needs of a wide range of healthcare professionals. According to Hayes et al. (2009) eHealth programme development should consider defining requirements in context, have the service user at the centre of all information systems, be localised, decentralised, integrated, use best of breed open sources components and make healthcare staff aware of the tactical benefits

of the programme. This highlights the need for careful consideration with deployment and implementation of eHealth intervention tools within the context of health care.

In Ireland Policy agendas are now targeting proactive healthier lifestyles. In 2013 the Irish government introduced a national framework entitled Healthy Ireland (DoH, 2013a). The Healthy Ireland framework aims to improve the health and wellbeing of the population of Ireland over the next twenty years. Healthy Ireland encompasses four goals related to the health and well-being of the population. The first goal is to increase the proportion of people that are healthy at every stage of life. Specific indicators of health relevant to this goal include health status, weight, obesity, tobacco use, alcohol consumption, physical activity, self-harm and mental wellbeing. Other factors, such as social connectedness or availability of and access to green spaces are also salient. The remaining goals prioritise reducing health inequalities, protecting the public from threats to health and creating an environment where each segment of society can be actively involved. This framework illustrates a trend toward targeting specific indicators of health and wellbeing in healthcare policy. The policy agenda is consistent across most EU member states as detailed in the Digital Agenda for Europe (European Commission, 2012) and the Healthy Life Course Project in Latin America and the Caribbean (Pan American Health Organization, 2014). A similar approach has been taken in the United States with the adoption of the Healthy People 2020 Initiative (US Department of Health and Human Services, 2010). In Ireland the Health Service Executive is investing in technology to support healthcare looking to the benefits of eHealth with the implementation of the knowledge and information strategy (Health Service Executive [HSE], 2015a) by the new Chief Information Officer of the HSE Richard Corbridge. This strategy forms the basis of the new eHealth Ireland website www.ehealthireland.ie grounded in clinical engagement (HSE, 2015b).

1.3: **Dementia**

The challenge of dementia has been recognized internationally and given the cost and implications there is an urgent need to be pro-active in prevention. This had led to the approach taken by In-MINDD to target the risk and protective factors associated with

dementia of individuals in mid-life. Dementia is an overarching term used to describe a myriad of symptoms including; decline in memory, reasoning, and communication skills and an on-going loss of the skills needed to carry out daily activities (The Alzheimer Society of Ireland, 2007). According to the Irish National Dementia Strategy (DoH, 2014) Alzheimer's disease accounts for a majority of dementia cases, the second most common dementia sub-type being Vascular Dementia. Less common dementia causes detailed by the DoH (2014) include mixed dementia (Alzheimer's Disease and Vascular Dementia), Dementia with Lewy Bodies, Frontotemporal dementia (FTD), Korsakoff's Disease, Huntington's Disease, Creutzfeldt-Jakob Disease (CJD) and HIV-associated dementia (HAD). Dementia is strongly associated with old age; although there are significant numbers within the overall dementia population with early onset dementia (beginning before the age of 65). Dementia is a global public health priority and is currently incurable. According to Prince, Guerchet, & Prina, 2013, there are 44 million people living with dementia globally, 7 million of whom are located in Western Europe. In 2013, Pierce, Cahill & O'Shea estimated there were approximately 48,000 people living with dementia in Ireland. Figure 1 amended from the Irish national dementia strategy (DoH, 2014) shows the expected increase in the numbers of people likely to present with dementia in Ireland. As can be seen from Figure 1 taking into account the steadily rising aging population by 2031 this figure is predicted to approximately double. Dementia is a costly condition both economically and socially. In Europe the total cost of dementia care in 2005 was estimated at €130 billion (Wimo & Prince, 2011) and in Ireland in 2010 the total cost was estimated be €1.6 billion per annum (Connolly et al., 2012).

Age group	2011	2016	2021	2026	2031	2036	2041	2046
30-59	2,866	2,935	2,934	2,869	2,854	2,864	2,889	2,991
60-64	1,200	1,301	1,449	1,615	1,738	1,906	2,044	1,896
65-69	2,776	3,287	3,827	4,020	4,485	4,876	5,315	5,645
70-74	4,604	5,532	7,013	7,442	8,367	9,378	10,211	11,188
75-79	7,475	8,213	11,298	12,560	14,055	15,928	17,968	19,692
80-84	10,958	12,265	16,099	17,868	22,348	25,364	29,102	33,196
85+	17,970	21,260	25,595	31,085	40,195	52,512	64,654	77,549
Total	47,849	54,793	68,216	77,460	94,042	112,828	132,182	152,157

Note: Estimates for 2011 based on Census of Population 2011. Projections for 2016 to 2041 based on CSO (2013) Population and Labour Force Projections, 2016-2014, Stationery Office, Dublin, Table 3, page 40 and EuroCoDe (2009) Age and gender specific dementia prevalence rates. (Source: Pierce, M. et al. (forthcoming). Prevalence and Projections of Dementia in Ireland, 2011. Genio Ltd., Mullingar).

Figure 1: Projected growth in the number of people with Dementia in Ireland by Age

1.3.1 Diagnosis

There has been much debate over the accuracy of increasing early dementia detection rates. It has recently been argued that figures quoted (see Figure 1) overestimate the increasing prevalence of dementia (Le Couteur, Doust, Creasey & Brayne, 2013). In recent years policy in the United States and UK has sought to increase rates of diagnosis of dementia and cognitive impairment through incentivisation (Le Couteur et al., 2013). Brayne & Davis (2012) indicate that the increase in the diagnosis of dementia and cognitive impairment in the UK is a direct result of the financial rewards offered to GPs. This policy drive has been accompanied by research into early detection of dementia but the ability of preclinical dementia features to predict future dementia disease is unclear (Naylora et al., 2012). Whereas policy makers in some countries are pushing for increases in early diagnoses of dementia; individuals diagnosed can then suffer from an array of increased health insurance costs, increased anxiety, depression and risk of unemployment (Boustani et al., 2008). Contrastingly early diagnoses of dementia can bring a number of benefits such as the ability to make important legal decisions including making a will, setting up an Enduring Power of Attorney (EPA),

setting up joint bank accounts and making social welfare payment arrangements (The Alzheimer Society of Ireland, 2015).

As dementia is currently incurable, a diagnosis can create an enormous sense of insecurity for individuals and their families. High levels of anxiety amongst middle-aged and older individuals worried about their memory, coupled with concerns about debilitation associated with dementia, makes dementia one of the most feared ageing-related conditions (Desai et al., 2010). Estimates suggest that the cost of nursing homes and home help is set to continue to rise with the elderly paying more for nursing home care (Cullen, 2015). Taken with the expected rise in elderly population and associated increase in the cost of elderly health care, staving off the effects of cognitive decline is becoming increasingly important for both financial and health reasons.

1.3.2 Policy

At an international policy level the WHO (2012) suggests that efforts to improve the quality and availability of care, and to seek a cure for dementia, should be accompanied by immediate investment in primary prevention measures. Barnes & Yaffe (2011) recommend that preventing the burden of dementia may be served better by efforts to decrease smoking and obesity, given recent research linking mid-life obesity and cigarettes with dementia risk. The Irish National Dementia Strategy (DoH, 2014) prioritises highlighting the modifiable lifestyle and cardiovascular risk factors which can beneficially impact on risk and time of onset of dementia through health promotion. Other priority actions from the National Dementia Strategy include promoting better public awareness and understanding of dementia by targeting populations that are at risk. The national dementia strategy (DoH, 2014) promotes the encouragement of physical activity by implementing the National Physical Activity Plan (in preparation) which will encourage the population to be more physically active. Some priority actions from the Irish National Dementia Strategy include promoting better public awareness and understanding of dementia by targeting populations that are at risk. There is much overlap between cardiovascular risk factors and the dementia risk factors identified by In-MINDD.

1.3.3 Dementia Risk and Protective Factors

Assessing dementia risk and protective factors is a complex problem. The aims of In-MINDD were to develop a multi-factorial model for dementia risk which would be used to produce the In-MINDD tool. Through a mixed-method approach a number of factors were identified which can enhance or reduce one's risk of developing dementia (see Figure 2). Deckers et al. (2015) describe the method which combined findings from a systematic literature review and a two round Delphi consensus study.
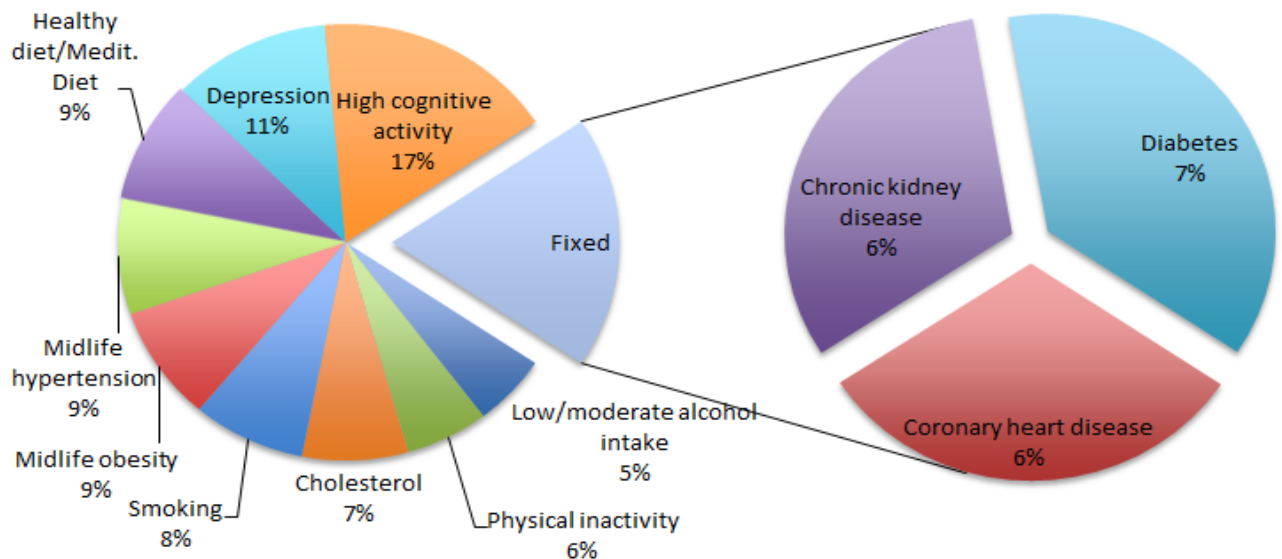
Figure 2: Dementia Risk and Protective Factors

The systematic review explored 3,127 abstracts investigating the best documented risk and protective factors associated with dementia. The Delphi study was carried out to reach consensus among experts on rankings for dementia risk and protective factors. Findings suggested that while some of the principal risk factors are non-modifiable, such as age, genetics and gender, a surprising number are modifiable. These include hypertension; cholesterol; obesity; alcohol consumption; smoking; and physical and cognitive activity (Desai et al., 2010; Kloppenburg et al., 2009; Hughes & Ganguli, 2009; Van den Berg & Splaine, 2012; Woodward et al., 2007). Factors that need to be managed or controlled through medication or lifestyle choices include chronic kidney disease, coronary heart disease and diabetes. According to (e.g. Arai, Arai and Zarit,

2008; Low and Anstey, 2009) among the general public there is awareness of age and genetics as contributors to dementia but less awareness about modifiable risk factors for developing dementia. In-MINDD takes a population health approach to cognitive health, described by the HSE (2014) as an approach which focuses on improving the health status of the population as a whole. In-MINDD seeks to improve cognitive health by targeting the awareness of interrelated risk factors that influence the health of populations throughout the life span. This introduction has provided an overview of the dementia risk and protective factors that form the basis of the In-MINDD tool. The next section provides the structure of the thesis.

1.4: **Thesis Organisation**

This thesis is presented in 9 Chapters including this Introduction Chapter. The structure of the thesis is as follows:

Chapter 2 reviews literature relating to aspects of eHealth and Personal Healthcare Records, the personalisation of healthcare, self-care and the wellness domain.

Chapter 3 appraises literature on the differing approaches to software and requirements development focusing on aspects of Human Centred Design, Service User involvement, Normalisation Process Theory and Usability Testing.

Chapter 4 outlines the philosophical assumptions of considered theoretical frameworks leading to the selection of critical realism. The methodological approach of Case Study is discussed and adopted to best address the main research question and identified aims of this study.

Chapter 5 provides account of the process of case selection, data collection methods and data analysis methods used. This chapter also outlines the process of seeking ethical approval for the present research and provides ethical considerations related to the research methods chosen.

Chapters 6 presents the case study findings of the requirements gathering process for the In-MINDD tool related to the information gathering phase of the research. This Chapter describes the information gathering research carried out with identified

stakeholders investigating stakeholder knowledge and the processes and communications involved with the In-MINDD tool.

Chapter 7 presents the findings for the Design in Process phase of the case study. Accounts are presented detailing the findings of GP interviews and service user focus groups. Key decisions and changes made to the design of the In-MIDD tool are related.

Chapter 8 describes findings of usability testing with service users to iteratively evaluate prototypes of the In-MINDD tool.

Chapter 9 returns to the research question and research aims in order to address them in light of the findings reported in Chapters 6-8. The discussion centres around the primary healthcare context, requirements development, optimising clinical engagement processes and on how best to optimise future versions of the In-MINDD tool. Conclusions are presented on the research process adopted and recommendations for further iterations of the In-MINDD tool and further research in the related area.

1.5: **Summary**

In this introduction the In-MINDD project background has been presented. The focus of this case study has been established as an investigation of the development of requirements for the In-MINDD tool. Background has been described on the risk and protective dementia related factors which the In-MINDD tool seeks to raise awareness of. I have clarified some of the key concepts and provided a breakdown of chapters to guide the reader.

Chapter 2: Literature Review

eHealth

2.1: Ubiquitous Computing and eHealth Interventions

2.1.1   Introduction

As the focus of this study is primary prevention and deterrence initiatives for dementia risk and protective factors this chapter will specifically review literature relating to aspects of eHealth, the personalisation of healthcare, self-care and the wellness domain. This chapter introduces the area of eHealth to the reader. Initially the expected benefits of eHealth in particular Personal Health Records (PHRs) are presented in Section 2.1, followed by Section 2.2 which explores and critically analyses a number of barriers and facilitators to the deployment of eHealth. Section 2.3 investigates how defining system requirements in context can enhance new eHealth interventions providing evidence from the summary care record. The chapter is concluded with some points to consider for the development of new eHealth interventions in Ireland.

2.1.2 eHealth and mHealth

Internationally there is widespread investment and growth in the complimentary fields of electronic health (eHealth) and mobile health (mHealth). Increasingly electronic health systems (eHealth) are provided on a number of mobile platforms such as tablets, portable and wearable devices, smart phones, smart watches and laptops (DoH, 2013b).

Contemporary healthcare delivery is expanding to include individually led, moving from healthcare managed and owned by the individual in addition to traditional healthcare service provision. Of particular relevance is the growth in mHealth, a contemporary and state of the art component of eHealth which is defined by the WHO (2011) as a medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, sensors, personal digital assistants (PDAs), and other wireless devices. Examples of mHealth include the use of smart phone apps or web applications which can be used to assess particular health and wellness related activity for example the World Heart Federation's (2015) Heart Age (http://www.heartage.me/) which can assess one's heart health by a simple assessment test.

2.1.3 Benefits of eHealth

eHealth interventions in most cases are centred on the patient and can be described as "patient centric". Many eHealth interventions are preventative rather than prescriptive with the aim of empowering service users to independently manage many aspects of their own health (Hutchesson et al., 2015). With the rise in mobile ubiquitous computing (smart phones, tablets, and portable devices) interventions of this kind can help the user to stay connected, become more autonomous and manage healthcare from multiple locations. This can serve to decrease GP visits, hospitalisations and lengths of stay and ultimately to reduce costs to the state (DoH, 2013b). eHealth systems utilise modern technologies and information systems to organize and integrate the delivery of healthcare. According to the eHealth strategy for Ireland released by the Departments of Health (2013b) a successful eHealth system should ensure improved patient outcomes, increase efficiency, increase transparency and enhance accessibility. eHealth systems include electronic health records (EHR), eprescribing, telemedicine, telehealthcare, automated pricing, performance, billing and claims management (Department of Health, 2013b).

2.1.4 CCIO

In Ireland the recently established Health Directorate in the HSE looks to information and communications technology as an enabler to support healthcare to optimise clinical effectiveness. To reap the expected benefits of eHealth, the implementation of the knowledge and information strategy (HSE, 2015a) has been published and new organisational structures have been launched. Critical to the new structures is clinical engagement which forms an integral part of the published knowledge and information strategy by the new Chief Information Officer of the HSE Directorate. There is a global trend to appoint Chief Information Officers (CIOs) for the strategic management of information through the use of information technology systems. In Ireland a Council of Clinical Information Officers (CCIO) has been established as an advisory group by the Office of the CIO and the eHealth Ireland committee (HSE, 2015c). The purpose of the

council is to provide clinical governance and oversight to the delivery of eHealth solutions and in particular the Electronic Health Record (EHR) Programme.

2.1.5 <u>PHR</u>

The ISO (2009) describe a Personal Health Record (PHR) as a repository of information considered by the service user to be relevant to one's health, wellness, development and welfare. The service user controls the PHRs content. Which is unlike an Electronic Health Record (EHR), where a nominated Healthcare Professional (HCP) has a mandate to provide health care activity for a subject of information. According ISO (2005) an Electronic Health Record (EHR) in its basic generic form is a repository of information regarding the health status of a patient updated by the clinician, in computable form. Healthcare Professionals can have access to PHRs but they are not responsible for them, the service user is. Recent findings from Ozok, Wu, Garrido, Pronovost & Gurses (2014) examined the usefulness and usability of a web based PHR application using a case study methodology indicating that service users find tailored health recommendations useful. Following use of the PHR application, service users went on to ask better informed questions of their healthcare providers. From the perspective of healthcare providers the PHR application was found to have content useful to service users, enhancing awareness of the relevant preventive health screening tests and lifestyle changes. The In-MINDD tool can be described as a self-care management web based PHR application aiming to enhance awareness of relevant preventive health screening tests and lifestyle changes among service users. Self-Care Management (Department of Health, 2005) is summarised here by the NHS UK as the way in which individuals take actions themselves to maintain both physical and mental health, in addition to meeting social and psychological needs.

2.1.6 <u>Low PHR Adoption Rates</u>

In 2011 research from the US indicated that despite the expected benefits of PHRs adoption rates were still relatively low with approximately only 10% of Americans using PHRs (Markle Foundation, 2011). There are, however, notable PHR success

stories from the US including the US Department of Veteran Affairs 'MyHealtheVet' and Kaiser Permanentes 'MyHealth Manager'. Nazi (2013) argues that to improve uptake of PHRs within the context of healthcare a deeper understanding is needed between healthcare interactions and how this influences the provision of services by healthcare professionals in organizational settings. Efforts to implement PHRs have traditionally been based on the idea that healthcare consumers will be empowered having increased control and access to health information leading to enhanced participation in health management (Nazi, 2013).

2.1.7 Consumer Empowerment

There are a number of expected benefits from eHealth system deployment initiatives such as reductions in costs due to less duplication of procedures and tests, less reliance on paper-based processes and current, accurate and timely electronic patient health records. The European Commission (2012) suggests that eHealth can help to facilitate socio-economic inclusion, equality, quality of life and service user empowerment through enhanced transparency, ease of access and information and the usage of social media for health. This is indicative of a trend in modern healthcare where some individuals are moving away from the role of passive recipients of care and migrating to empowered proactive consumers of care who exercise choice and manage their own health outcomes. Core motivators for uptake and use by consumers are listed as access to health information and telehealth services and an ability to influence and contribute to personalised health care plans (DoH, 2013b).

2.1.8 <u>eHealth Strategy Ireland</u>

The eHealth strategy for Ireland 2013 (DoH, 2013b) suggests that it is critical that all players exemplified in Figure 3 are actively engaged from the outset of an eHealth project to produce success. The eHealth strategy recommends that in order to utilise an eHealth solution planning and execution need to be based on a number of critical factors. There needs to be a recognized business need for a product with embedded planned transition and change management initiatives such as process reorganisation and adaptation of workflows to optimise impact and benefit realisation.
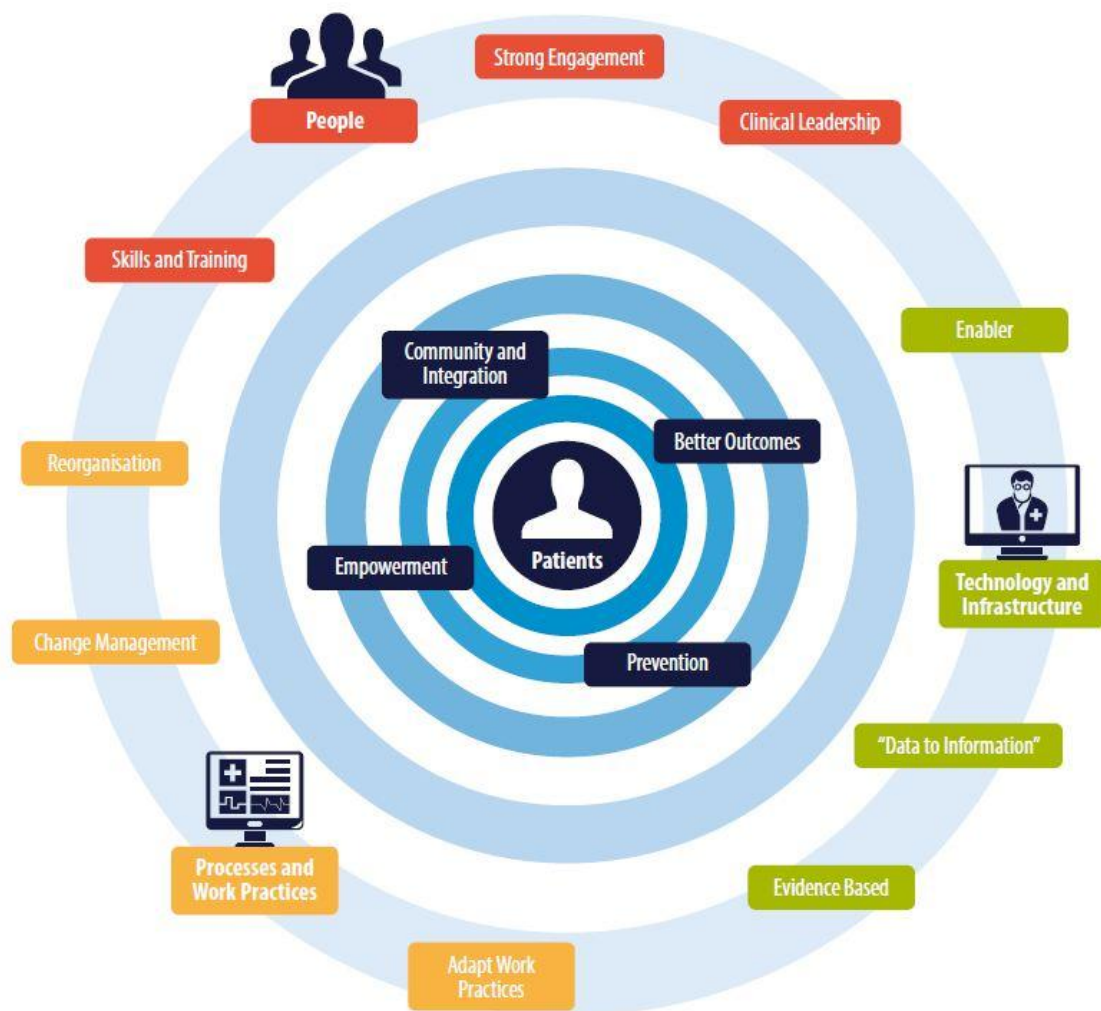
Figure 3: DoH (2013b) Key Players in Successful eHealth Deployment

2.2: **Barriers and Facilitators to the Deployment of eHealth**

Recent European Commission publications on the Digital Economy and Society Index (DESI) in Europe report both that the European Union as a whole as well as individual Member States are progressing towards a digital economy and society. Denmark, Sweden, The Netherlands and Finland are the highest performing countries and are noted not only ahead in the European Union, but they are world leaders in the digital agenda (European Commission, 2015). The Digital Agenda is made up of 100 comparable key indicators of the European information society divided into thematic groups such as Telecom sector, Broadband, Mobile, Internet usage, Internet services, eGovernment, eCommerce, eBusiness, ICT Skills, Research and Development (European Commission, 2015). This move towards a more digital economy and society has important implications for the deployment of eHealth. Barriers and facilitators to the deployment of eHealth will now be reviewed including legislation, data protection, Individual Health Identifiers, Electronic Health Records and Meaningful Use incentives.

2.2.1 Legislation

Given that eHealth interventions are for the large part viewed by governments with such optimism, it is salient to attend to the types of obstacles that new eHealth interventions face. These types of obstacles include but are not limited to issues of awareness and dissemination, ICT, legal issues and financial issues (European Commission, 2012). The European Commission (2012) suggests that a reduced awareness of, and confidence in eHealth solutions can impede uptake among new users. ICT can present its own set of challenges such as poor interoperability defined by ISO (2005) as the ability of two or more systems to exchange information. In lower socio economic areas ease of access to ICT is problematic in addition to regional differences both within a country and across borders. New eHealth initiatives also need to be aware of extensibility or the ability of systems like the In_MINDD tool to extend in the future (Xiao et al., 2010).

2.2.2 Data Protection

From a legal standpoint a number of barriers surround the data controlled and processed by eHealth applications and there is a need for transparency regarding how personal data is protected and used (Data Protection Commissioner, 2003). Recently the EU have

questioned Ireland's data protection neutrality, claiming that Ireland was leading a push on light touch data protection controls to appease multinationals such as Facebook (Cahill, 2015). EU data protection legislation is expected to bring equal digital rights across the EU insisting that individuals must actively agree to have their data shared, have the right to access their own data, to be forgotten, to be erased, and to object to what is being held (Cahill, 2015). Transatlantic eHealth initiatives such as the In-MINDD project need to be aware and plan for a near future where all EU citizens will have the same digital rights.

2.2.3 IHI

Recent legislation in Ireland has enacted the Health Identifiers Act 2014 (HIQA, 2014) which legislates for the creation of the Individual Health Identifier (IHI). An IHI is defined by HIQA (2014) as a lifelong unique, non-transferable number given to all individuals using health and social care services in Ireland. The IHI will be used to identify individuals with increased accuracy, ensuring health and social care is delivered to the right service user, in the right place and at the right time. The advantages of an IHI are purported to be a safer, better quality and reliable healthcare system. New Irish eHealth initiatives stand to benefit from IHI compatibility claimed to be a key enabler for the successful deployment of an eHealth infrastructure (Mudiwa, 2015). The Health Information Bill enacted in quarter four of 2015 has provided the legislative framework for the governance of information in the Irish health sector (Gantly, 2014).

2.2.4 eHealth Start-up Costs

Financially speaking there is a lack of evidence regarding the cost-effectiveness of new eHealth applications and start-up costs can be expensive. Historically the European Commission (2012) reports that there can be poor legal frameworks including lack of reimbursement schemes for eHealth services. When faced with a number of barriers many new eHealth applications fail to be implemented and successfully integrated in practice (European Commission, 2012). With regard to defining requirements for the In-MINDD tool chances of successful implementation and integration could be improved by a coordinated and focused attempt by a broad number of stakeholders to address the barriers listed by the eHealth Action Plan (European Commission, 2012).

2.2.5 <u>EHR and User Participation</u>

Sufficient requirements analysis is required to enhance the chances of success for a new eHealth system or intervention. Globally, healthcare systems have been endeavouring to make patient records electronic with varying degrees of success since the mid 1990's (Blumenthal & Tavenner, 2010; Brennan, Casey & Saranto, 2009; Mair et al., 2012). Watson (2010) states that oftentimes the implementation of eHealth strategies proving to be much more complex and time-consuming than previously expected. Bossen (2011) suggests that a new EHR which is a central component of any eHealth system can fail to deliver anticipated benefits despite the aid of clinicians during the development and implementation phases. Bossen analysed a prototype EHR based on the Danish national electronic health record standard entitled the Basic structure for Electronic Health Records (BEHR). The BEHR attempted to standardise clinical information systems to a set of national standards. Clinicians were consulted during the co-design process and took part in prototype testing. Yet in the case of the BEHR clinicians found the standard inappropriate for their work (Bossen, 2011). Before the prototype tests, the clinicians involved stated that the BEHR represented their way of thinking and working. BEHR prototype tests provided evidence of increased accountability with the detrimental effects of increased work load, loss of overview and fragmentation of patient cases. The case of the BEHR helps to highlight the challenges of user participation in the co-design of eHealth systems. Bossen (2011) concluded that co-design processes should include users as representatives of a profession, whilst striving to produce experiences and knowledge intrinsic to practice. This highlights the importance of gathering information from a number of different sources when developing requirements for the In-MINDD tool.

2.2.6 <u>Meaningful Use</u>

Similarly in the United States the transition from a paper based health record to EHR has proved an enormous and complex task that challenges the way health care providers and hospitals document, monitor, and share information about health and care provision (DesRoches et al., 2013). In 2010 the US government introduced an incentivized system called "Meaningful Use" (MU) to seek to ensure that EHR technology significantly

improves service user health care (Blumenthal & Tavenner, 2010). The MU scheme operates by providing payments to the state run medical and health related services (Medicare and Medicaid) that can prove that they are "meaningfully using" their EHR by satisfying a number of criteria. According to DesRoches et al. (2013) based on evidence from a longitudinal survey of US hospitals investigating the adoption rates for EHR systems just 44 percent of hospitals report having and using what was defined as at least a basic EHR system. A rural/urban divide was noticed with large urban hospitals having significantly improved EHR systems adoption rates compared with rural and nonteaching hospitals. Increased EHR adoption rates in the US can be attributed to the Meaningful Use (MU) scheme yet there is still an un-even uptake of EHR systems (DesRoches et al., 2013). More recent reports indicate two percent of eligible physicians and about one in six hospitals having successfully met stage 2 requirements for MU stage 2 (Wachter, 2014). Notwithstanding this MU incentives have proved somewhat successful. Watcher suggests that MU stage 3 should promote interoperability over prescriptive aggressive requirements standards that are unattainable in the real world. Similarly a systematic review by Studeny & Coustass (2014) found MU incentives to have increased PHR data silos leading to a lack of interoperability. When investigating eHealth barriers an important obstacle to attend to is the importance of defining system requirements in the context in healthcare. Context therefore has a significant impact for optimising requirements and will be of central importance to this study.

2.3: **Importance of Defining System Requirements in Context**

Lack of sufficient requirements analysis has been identified as one of the most common reasons for the failure of a large number of clinical systems and projects (Heath & Luff, 2000). Van Velsen, Wentzel, & Van Gemert-Pijnen (2013) agree that a mismatch between the eHealth technology and context of use can lead to the faulty use of technology, user dissatisfaction, low adoption rates and or a poor return on investment. Seminal work by Berg (1999) argues that a significant number of patient care information systems fail to make it past the design phase. Moreover patient care information systems consistently fail to be transferable out of the context in which they were created.

2.3.1 <u>Lessons learned from NPfIT</u>

The UK's National Programme for Information Technology (NPfIT) was the largest civilian IT project ever undertaken and an example of a major eHealth project failure (Hayes et al., 2009). The NPfIT began in 2002 and was dismantled in September 2011. The NPfIT did, however, provide the NHS with the National Spine Services being a national exchange of information incorporating a collection of national applications, services and directories (Health and Social Information Centre, 2015a). The project was originally expected to cost £2.3 billion over three years but was finally estimated to have cost £12.7 billion (Hayes et al., 2009). The project was envisioned as a single nationally imposed system or central spine of data but failed to meet the requirements of the NHS. One of the contributing factors that led to the failure was the top down approach taken by management which did not fit local clinical practitioner and client's needs. The programme was replaced by a number of less costly regional initiatives whereby hospitals and GPs choose their own IT system. In 2009 the British MP Stephen O'Brien commissioned an independent review of the NPfIT. The review group reached a number of conclusions as to how NPfIT was failing. Hayes et al. (2009) concluded that; the patient should be at the centre of all information systems, IT systems should assist both patient and clinician in the care of the patient and delivery of care, new healthcare programmes should be open to localisation and be decentralised so that health data is stored closer to the point of patient care and that information systems need to be interoperable. Hayes recommended that the deployment of IT is primarily a change management programme needing clinical engagement to achieve change. It is important for stakeholders engaged in eHealth strategy initiatives to be mindful of scandals like the Francis inquiry into hospital failures in Mid Staffordshire (UK) where systematic failures in patient care were found due to focus on cost cutting and hard hitting government targets (Boseley, 2010).

2.3.2 <u>Summary Care Record UK</u>

One aspect in which significant progress has been made in UK NHS is the Summary Care Record (SCR), and the main secure patient database and messaging platform NHS Spine. NHS Spine1 had run on an Oracle platform, as a single multinational technology

supplier under an out-sourced contract managed by telecoms giant BT Global Services. In response to the changing needs of the NHS, Spine1 was rebuilt with the aid of open source participants allowing local users of the system to fix problems at will (Clarke, 2014). Open source software (Open Health Informatics, 2013) is software that can be run for any purpose and whose source code is available for adaptation or improvement by anyone. The use of interchangeable, best of breed open source components has allowed the NHS healthcare system to move away from a single technology proprietary code supplier such as Oracle. In this way the NHS has moved to take advantage of general open source software specifically to meet healthcare requirements (Open Health Informatics, 2013). The Spine2 contract was awarded under the British Cabinet Office's G-Cloud framework, which encourages government employees to buy from small providers (Clarke, 2014). The Summary Care Record (SCR) is an electronic record containing information about patients including allergies, medications and adverse reactions. It is pulled from GP systems which can be viewed by health professionals involved in a patient's care. Improvements in the SCR have proved to have demonstrable benefits to patient safety, efficiency and clinical effectiveness (Health and Social Information Centre, 2015b).

2.3.3 eHealth and Benefits Realization

The concept of benefits realization (Peppard, Ward & Daniel, 2007) proposes that healthcare staff need to be made aware of the tactical benefit technology can provide for enhanced healthcare solutions. Clinical staff should not view the eHealth system processes as solely systems for data collection. Hayes et al. (2009) identified the evaluation process for improvement. Systematic and iterative evaluation rather than one-off assessment were recommended. It was suggested that evaluation focus on the end user (clinician/healthcare worker) taking into account their views and opinions. Systems should be piloted and evaluated from an un-biased perspective whereby the implementation of systems is not a foregone conclusion. Local skills and expertise should be accounted for during design and development phases. The technology should be amenable to localisation described by Rouse (2005) as the process of adapting a product or service to a particular language, culture, and desired local look-and-feel.

Hayes et al. suggested the consideration of alternatives to one monolithic central spine of data so that health data is decentralised or stored closer to the point of patient care. Furthermore it was suggested that information systems need to be interoperable, addressing both functional and semantic requirements. It was suggested that smaller providers should be encouraged to innovate and develop solutions that better meet the needs of service users and the clinicians providing their care (Hayes et al., 2009). The recent initiative in Ireland to the develop of the Council of Clinical Information Officers (CCIO) to the HSE Directorate Authority, described in Section 2.1.4,will provide constructive advice to ensure benefits realization will be optimized in the Irish Healthcare setting.

2.3.4 <u>Human Centered Approach</u>

The concept of benefits realization has commonalities with the Human Centred Design (ISO, 2010) approach to defining system requirements. According to Van Velsen et al. (2013) the creation of requirements is oftentimes left to developers who apply a technology driven approach. In order to produce a successful eHealth project Van Velsen et al. suggest that a multi-disciplinary team apply a human-centred approach. The approach should be cognisant of the organisational and individual contextual specifics into which the technology is to sit. The WHO (2010) concluded that the mismatch between context and technology accounts for up to three quarters of new medical device failure. Bearing this in mind, a clear understanding of the context into which a new system or intervention will sit can provide an increased chance of successful implementation and integration.

From an informatics perspective successful implementation of an integrated eHealth solution for the In-MINDD tool needs to be cognisant of a number of critical factors. Both the social features of the current work practice and the technical features of the system have to be considered when performing requirements gathering and analysis (Reddy, Pratt, Dourish, & Shabot, 2003). For example social factors may include political, ethical, social and organisational issues. Technical factors may include architecture processes, structures and semantics. Actively involving the users in the design process through methods such as participatory design can help to improve

sociotechnical requirements analysis and therefore provide justification for the current research. Taking into account these factors can provide a more focused evaluation framework which can be used to provide a basis for improved implementation and integration of a new eHealth intervention. Furthermore, following the implementation phase an evaluation framework can be used to appraise if the anticipated benefits were achieved in context.

2.3.5 The Healthcare Consumer

With the ever increasing use of EHRs access to and control of patient information is more important and topical than ever before (Meslin et al., 2013). As indicated by the DESI (European Commission, 2015), the European Union (EU) is progressing to a more digital economy and society with important implications for healthcare. Individuals have more choices and are becoming more involved with their own health through the use of mobile devices (European Commission, 2015). Findings from a US survey of 2,339 residents report that young consumers (under the age of 45 years) prefer digital communication with healthcare providers and insurers over traditional visits or phone calls (Estupiñán, Kaura & Fengler., 2014). McEvoy (2014) has recently suggested that we are in the midst of a paradigm shift where changing power roles in healthcare are being observed. Some individuals are no longer passive recipients of healthcare but healthcare consumers. Healthcare consumers can act as active participants in healthcare management and will exercise choice in what service providers to use. Healthcare consumers are typified as being educated, mobile, and actively seeking different healthcare options. An example of this changing paradigm is the growing proportion of service users using information accessed online to educate themselves before a GP consultation (Meslin et al., 2013). EHRs store and transmit data electronically, via regional Health Information Exchange profiles (HIE) which are accessed by many healthcare providers and insurers (Meslin et al., 2013). Healthcare initiatives and oversight bodies need increased access into existing patient health records to feed growing consumer demand for more personalised healthcare. Service user access to and control over their individual health records and information is particularly topical and requires focused attention for eHealth initiatives such as In-MINDD.

Being cognisant of the evidence presented in this chapter, future activities relating to the development of any eHealth initiatives developed for primary care use in Ireland should consider:

- Careful requirements definition in context.
- Location of the service user perspective at the centre of all information systems.
- Ensure system requirements are capable of being localised, decentralised, and interoperable.
- Should adopt use of best of breed and open sources components.
- Support increased awareness for healthcare staff of the tactical benefits of the programme.
- Support a Human Centred Approach
- Be compatible with the recently enacted legislation on the Individual Health Identifier.
- Be inclusive with representation for both health care professionals and the service user.
- Give the service user more control of health data.

2.3.6 <u>Summary</u>

This chapter reviewed literature in the area of eHealth more specifically the barriers and facilitators to the deployment eHealth initiatives such as Personal Healthcare Records. A number of important points with regard to defining system requirements in context were reviewed. Chapter 3 builds on this basis and expands the literature review to include analyse of different approaches to the software development lifecycle and eHealth requirements development.

Chapter 3:

Literature Review Requirements
Development Process

3.1: **The Software Development Lifecycle**

3.1.1 Introduction

This chapter explores the agile and waterfall methodologies as approaches to software development. Material is explored from the perspective of how it relates to the In-MINDD tool requirements development process. Specifically, the area of Human-Centred Design (HCD) is explored and how it relates to requirements gathering from an agile perspective. Types of requirements gathered such as functional and non-functional requirements are explained. The chapter then progresses to discuss how user involvement can enhance the eHealth software design process. Different information gathering methods used to elicit requirements are investigated particularly observations and semi-structured interviews providing grounding for the methods discarded and chosen to elicit requirements described in Chapter 5. The Normalisation Process Theory (NPT) evaluation framework as described by May et al. (2010) is discussed as useful to identify factors that facilitate and restrict the routine incorporation of complex interventions such as In-MINDD into daily practice. This framework is important as it can be used to investigate the requirements elicited for the In-MINDD tool as they relate in Chapters 6-8. To conclude this chapter decision support systems are reviewed as a key feature to support risk prevention initiatives.

3.1.2 Agile and Waterfall Software Development Methodologies

A number of software development lifecycle methodologies exist, but broadly speaking software development can be grouped into two camps, the waterfall methodology and the agile methodology. The agile method of software design proposes the development of software with a small team of experts and end users and the use of rapid prototyping that is constantly evaluated and redesigned (Beck et al., 2001). Agile is epitomized by repeated consultation loops with the end user quickly delivering working software with little reliance on comprehensive documentation (Bell, 2005). Beck cautions, however, that agile may not be applicable to all settings particularly the healthcare setting as it can be time consuming having an impact on service user safety and emotional wellbeing of

healthcare workers and service users. Additionally, it may prove challenging to repeatedly consult in a dynamic fast paced healthcare setting due to workload pressures and competing agendas with end users and healthcare staff time (Beck et al., 2001).

Figure 4 amended from (HeightsIT, 2014) illustrates how with an agile methodology testing begins at an early stage.
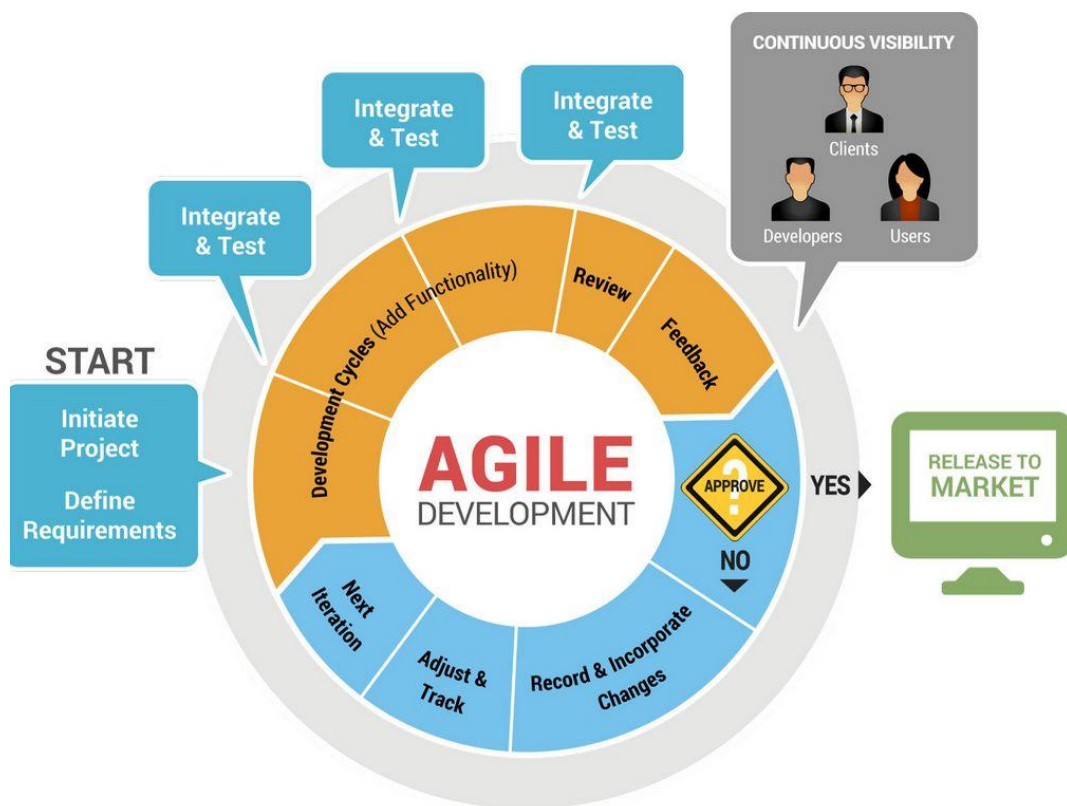
Figure 4: HeightsIT, (2014) Agile Methodology

A Health care practitioner's core responsibility is on realising optimal service user outcomes and safety management. The primary goal for the service user and health care professional should be to maintain existing health state or improve their overall health and wellbeing. Such competing priorities can therefore be difficult for a researcher to align with, particularly in regard to systems requirement specifications. In contrast to the agile method, the waterfall or the linear-sequential life cycle model approach described by Royce (1970) is a traditional phased approach to software design. Figure 5 presents a diagram of the traditional waterfall model proposed by Royce and as can be seen phases cascade downwards hence the name waterfall.
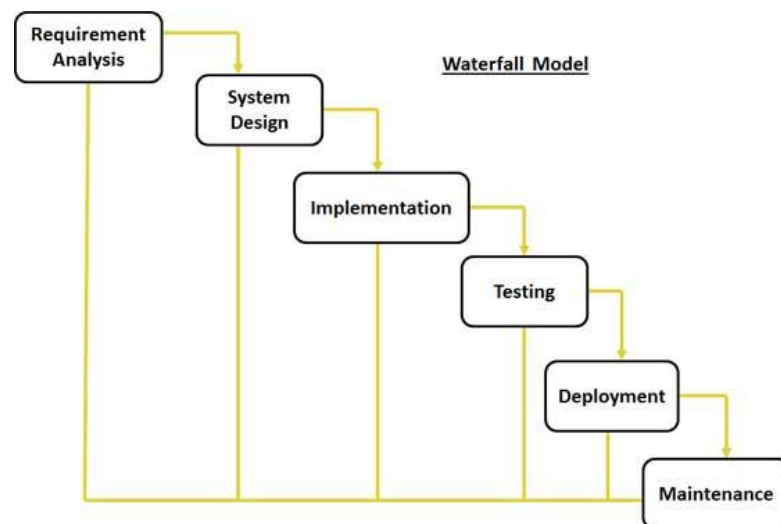
Figure 5: Traditional Waterfall Model

The phases of the waterfall model espoused by Royce include: (1) Requirement Gathering and analysis, (2) System Design, (3) Implementation (4) Testing (5) Deployment of system (6) Maintenance. In the traditional waterfall model all possible requirements are elicited during the requirement gathering and analysis phase leading to the creation of a requirements specification document. Requirements from the first phase are examined in the system design phase where hardware and system requirements and system architecture are specified. Following the implementation phase

the complete system is then tested for any bugs or failures. When the functional and non-functional testing is complete, the product is deployed. Ideally the waterfall phases do not overlap as phases would in the agile approach; however there can be many iterations of the loop in analysis, design, implementation and testing. In this model the testing starts only after the development is complete which leads to risks with measuring performance. The waterfall approach is applicable when project timelines are short, requirements are very well documented or not frequently evolving and there are ample resources and expertise available to support the product (Tutorialspoint, 2015). The problem with waterfall as (Bell, 2005) puts it is that the gap between requirements gathering at the early stage and testing is too big. In short, the waterfall methodology can be described as design, build and then test, whereas with agile one tests, builds and designs.

3.1.3 Agile and Human-Centred Design Principles

In recent software development literature the concept of user experience (UX) is taking on an increasingly important role to enhance the experience of the user (Yusuke, Masakazu & Hisashi, 2014). Yusuke, Masakazu & Hisashi, (2014) found applying Human-Centered Design (HCD) principles as specified in the International Standard ISO9241-210 (ISO, 2010) a successful means of enhancing UX. The flexibility that agile software development offers coupled with the principles of HCD have been evidenced to improve UX and provide scope to make priority changes at the development stage (Yusuke, Masakazu & Hisashi, 2014). The software development of the In-MINDD tool followed an agile methodology while incorporating human-centred design processes.

3.1.4 Human Centred Design

The ISO (2010) 9241-210 standard concerns the ergonomics of human-system interaction specifically human centred design processes for interactive systems. This industry standard has been determined by international consensus and provides a high level overview of the activities that are recommended by experts in the field of human centred design. The standard describes principles that serve to ensure design is user centered which are:(1) being based upon an explicit understanding of users, tasks and

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environments, (2) user being involved throughout design and development (3) driven and refined by user-centered evaluation (4) process is iterative (5) addresses the complete user experience (6) having a multidisciplinary design team.

The HCD standard's principles amended by Travis (2011) are explained here in more detail. System design researchers are implored to understand context of use through understanding users, understanding what the users want to do with the system (tasks) and understanding the physical and social environment in which the product is used. The ISO 9241-210 standard espouses that users be actively engaged throughout all phases of the design and development of a new product. The process should be iterative as there needs to be a continuous back and forth communications with identified key stakeholders. The design should be driven and refined by user-centred evaluation carried out throughout the design process testing preliminary designs such as paper prototypes and electronic mock-ups. The design team should include various members with differing perspectives, including the voices of accessibility experts, end users, domain experts, marketing, tech support, technical writers and business analysts.

According to Koivunen & May (2002) heuristic evaluation is conducted to find the usability problems in design which can be taken into account as part of an iterative design process. Creating a set of user scenarios at the beginning of the process will help the software designers to consider the problems that the users will be dealing with. ISO (2010) describes seven processes each of which contain a set of base practices describing what has to be done in order to account for and include system users presented in Table 1.

Table 1: Human-centred design processes and their base practices ISO 9241-210

ISO 9241-210 Human-centred design processes and their base practices			
1	**Ensure HCD content in system strategy**	**5**	**Produce design solutions**
1.1	Represent stakeholders	5.1	Allocate functions
1.2	Collect market intelligence	5.2	Produce composite task model
1.3	Define and plan system strategy	5.3	Explore system design
1.4	Collect market feedback	5.4	Use existing knowledge to develop design solutions
1.5	Analyse trends in users	5.5	Specify system and use
2	**Plan and manage the HCD process**	5.6	Develop prototypes
2.1	Consult stakeholders	5.7	Develop user training
2.2	Identify and plan user involvement	5.8	Develop user support
2.3	Select human-centered methods and techniques	**6**	**Evaluate designs against requirements**
2.4	Ensure a human-centered approach within the team	6.1	Specify and validate context of evaluation
2.5	Plan human-centered design activities	6.2	Evaluate early prototypes in order to define the requirements for the system
2.6	Manage human-centered activities	6.3	Evaluate prototypes in order to improve the design
2.7	Champion human-centered approach	6.4	Evaluate the system to check that the stakeholder and organizational requirements have been met
2.8	Provide support for human-centered design	6.5	Evaluate the system in order to check that the required practice has been followed
3	**Specify the stakeholder and organisational requirements**	6.6	Evaluate the system in use in order to ensure that it continues to meet organisational and user needs
3.1	Clarify and document system goals	**7**	**Introduce and operate the system**
3.2	Analyse stakeholders	7.1	Management of change
3.3	Assess risk to stakeholders	7.2	Determine impact on organisation and stakeholders
3.4	Define the use of the system	7.3	Customisation and local design
3.5	Generate the stakeholder and organisational requirements	7.4	Deliver user training
3.6	Set quality in use objectives	7.5	Support users in planned activities
4	**Understand & specify the context of use**	7.6	Ensure conformance to workplace ergonomic legislation
4.1	Identify and document user's tasks		
4.2	Identify and document significant user attributes		
4.3	Identify and document organisational environment		
4.4	Identify and document technical environment		
4.5	Identify and document physical environment		

The different forms of software development reviewed here provide a basis for the development of requirements, production of a design solution, implementation and testing of said design solution in this case the In-MINDD tool. No one methodology was strictly adhered to for the In-MINDD project, a hybrid approach was adopted. The software development for the In-MINDD tool followed an agile methodology

incorporating HCD principles with repeated consultation of the client (the In-MINDD research team) and the programmer.

3.1.5 Functional Requirements

Following the ISO (2010) definition functional requirements specify what a system should do. Functional requirements should form a complete and unambiguous description of software products functionality. Functional requirements are descriptions of actions a product must take such as check, calculate, store, record, retrieve. In order to produce requirements Robertson & Robertson (2012) ascribe the use of the trawling technique and the method of producing use cases in order to derive functional requirements. Trawling is advised by Robertson & Robertson (2012) in order to open a dialogue with users. Trawling is carried out to gain knowledge of the work that the user currently does and to determine the work that the user/stakeholder desires of the program in the future. Use cases involve writing scenarios that separate interactions by an actor with the program into a number of steps. In order to elicit requirements the researcher examines each step to derive the functional requirements and produces a report which specifies unambiguously all requirements for the system's functionality.

3.1.6 Non-Functional Requirements

Non-functional requirements specify how the system should do something. Non-functional requirements also known as 'quality in use' requirements and are related to the subjective experience of the user while using the system. These are the qualities that make a product usable, attractive, fast, or reliable. Quality in use can be broken down into functionality, reliability, usability, efficiency, maintainability and portability. An example of non-functional requirements for a product is that it responds in a specified time or has a particular look and feel (Robertson & Robertson, 2012). They should only specify the external behaviour of the system and should avoid, as far as possible, system design characteristics.

3.1.7 <u>User Requirements Specification</u>

User requirements should be understandable by all users and therefore be written in simple language, instead of software jargon, aided by diagrams and tables (Robertson & Robertson, 2012). A User Requirements Specification (URS) Document describes what users require from the system. A URS is written early in the validation process, usually before the system is formed. User Requirements Specifications are intended to be non-technical and readable by those with only a cursory knowledge of the system should be able to understand the requirements outlined in the URS (Robertson & Robertson, 2012). The URS therefore provides a framework for communication between all stakeholders engaged in development and use of the system

3.2: **eHealth Requirements Development**

Requirements development and analysis as described by Van Velsen et al. (2013) is a crucial part of eHealth design. Typically this process involves detailing all the activities related to identifying requirements, and the dissemination of functional and output based requirements to developers and then evaluating the process. This underpins the foundation of technology design. Requirements describe what a technology should do, what data it should store or retrieve, what content it should display and what kind of user experience it should provide. The justifications for good requirements development include the following reasons; (1) the involvement of end users and stakeholders in the creation of requirements has been proven to be effective (2) it improves usability and prevents inclusion of redundant features (3) it can prevent over spending on poor design.

3.2.1 <u>Information Processing</u>

One related example of tools that can be used to elicit and analyse requirements for health care using mobile device technology include Sørby, Melby, & Seland, (2005) input-process-output (IPO) information processing model. In one study Sørby et al. (2005) applied two different requirements gathering techniques to elicitelicit requirements for a new mobile electronic patient record (EPR) system used in hospital

wards. An EPR is defined in this case as a computer system designed to support clinicians by providing accessibility to complete and accurate patient data often associated with one acute service or organisation (Sørby et al., 2005). Numerous EPR systems exist, most of them developed for stationary computers, but also provided on multiples of other devices such as tablets or handheld computers. In this study both structured observational frameworks and drama improvisations were used to gather requirements. Both techniques were based on HCD and participatory design principles, and were developed and used as part of the MOBEL (Mobile Electronic Patient Record) project at the Norwegian University of Science and Technology. Observational studies were found useful for understanding the complexity of organisations and the various information needs of different users. Sørby et al. (2005) demonstrated how to apply frameworks to scenarios which can then be used for producing requirements for a mobile EPR. Illustrating the types of challenges that can arise when moving from paper-based systems to computer based systems Sørby et al. (2005) included making decisions around the types of information that should be included in a system and how this information is then presented.

3.2.2 Human Centred Design

Poor user interface design has been identified in several studies (Shah & Robinson, 2007; WHO, 2010; Zhang & Patel, 2006) as a barrier to the acceptance and routine use of a number of different computing systems in healthcare. Service user involvement has been evidenced to significantly enhance user interface design resulting in products that better suit then needs of service users (Shah & Robinson, 2007). User involvement can, however, prove difficult due to non-availability of key users coupled with time and cost constraints (Shah & Robinson, 2007). In order to overcome the challenges of creating user friendly, intuitive and efficient computer programs and applications, in the case of the In-MINDD tool, an online self-care management Personal Health Record tool it is essential to know and understand fully the context of use. The reasoning behind providing the In-MINDD as a PHR is discussed at length in Chapter 6. Sørby et al. (2005) examined HCD as an approach to interactive system development that specifically focuses on making systems and interfaces user friendly. The main

components of the human-centred system development cycle are illustrated in Figure 6 below. Points *3"specify the user and organisational requirements"* and 5 *"evaluate design against requirements"* are of particular interest to this research.
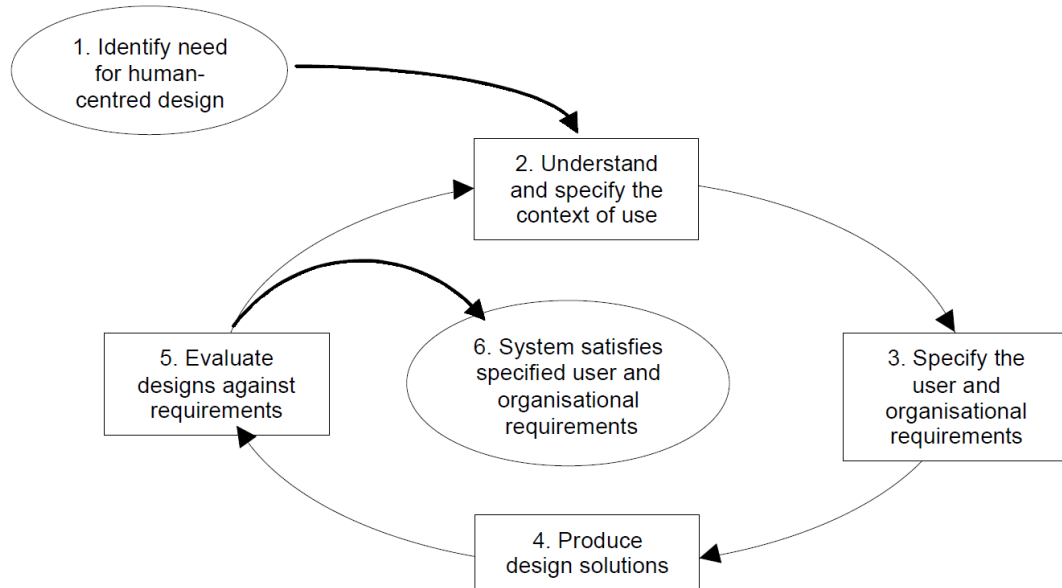
Figure 6: ISO Standard for Human-Centered Design processes for Interactive Systems

Sørby et al. (2005) argue that utilising insights gained from observational research to inform systems design is a major challenge. In order to overcome the challenge of converting observational studies to design decisions Sørby et al. constructed detailed scenario descriptions of current work practise situations in order to perform requirements analysis. A scenario was described as a description of a process or a sequence of acts in a narrative form (Kuutti, 1995). Sørby et al. provides an example of a way to create a framework for structuring and analysing scenarios. Example scenarios are presented in Figure 7.

Figure 3a. Example scenario 1

S1: Pre-rounds conference per patient

The pre-rounds conference is held every weekday prior to the ward rounds. One or more physicians and nurses (typically the head physician, one assistant physician, and the team leader nurse) from the care team discuss the care plans of the patients based on the patient chart, possible new test and/or examination results, and supplementary information from the nurse documentation or undocumented information from the participants of the conference. The nurse has a notebook called "ward rounds book" in which he or she registers the tasks of the ward secretaries and the nurses; for instance, if there has been a change in the medications of a patient or if a patient is to be discharged or moved to another ward.

Figure 3b. Example scenario 2

S2: Ward rounds incident: Seeking new test results

One of the patients wants to know his haemoglobin percentage. The nurse returns to the office to check the latest laboratory answers, but due to a mistake the test was not ordered in the morning. The consequence is that the patient has to take an additional blood sample, and the physician has to remember to check the result of the test when it becomes available.

Figure 3c. Example scenario 3

S3: Medication - per patient

One of the nurses in the patient care team uses information from the patient chart to put today's medications for the ward patients onto a medicine tray. Later the nurse in charge inspects the medicine tray to ensure that the medicines correspond to the recorded information on the patient chart.

Figure 7: Sørby, Melby, & Seland, (2005) Scenario Examples

3.2.3 Inputs, Process, Output Model

Sørby et al. (2005) set out to identify scenarios that would improve, become more efficient or be removed with the introduction of the mobile EPR. Preliminary attributes that were considered important for structuring and formalizing observations were defined. The information attributes were arranged into three parts; process attributes, input attributes and outcomes see Table 2.

Table 2: Sørby, Melby, & Seland, (2005) Applying observation framework to ward scenarios

	Attribute	S1	S2	S3
Process	Number of participants	2-4	2-4	2-4
	Number of roles	Several	Several	Two
	Number of role levels	Several	Several	Two
	Composition	Predetermined	Ad-hoc	Predetermined
	Decomposition	No	No	Yes
	Scenario nature	Semi-formal	Informal	Formal
	Regularity	Daily	Occasionally	Daily
	Scheduling	Well in advance	On the spot	On the spot
	Variance of required information	A lot	No	Somewhat
	Location(s)	Predetermined, varying	Multiple	Predetermined, fixed
	Spatiality	One place	Two places	One place
	Temporality	Synchronous	Asynchronous	Asynchronous
	Information exchange	Many-to-many	One-to-many	One-to-many
	Initiation	On demand	On demand	On demand Precondition
	Delay tolerance of scenario start	None	None	None
Information input	Novelty	To some	To all	To some
	Recorded	Personal notes Patient record forms	Patient record	Patient record
	Longevity	Short & long term	Long term	Short term
	Medium/mode	Speech & text	Text	Text
	Scope	All	Some	All
	Delay tolerance of input information	None	None	None
Outcomes/produced output	Explicit	Yes	Yes	Yes
	Shared	Yes	Yes	Yes
	Novelty	To some	To all	To some
	Recorded	All types	Patient record Personal notes	Patient record
	Longevity	Short & long term	Long term	Long term
	Type of produced information	Constructive Cooperative Coordinating	Constructive	Cooperative Constructive
	Medium/mode	Speech & Text	Speech & Text	Text
	Scope	Patient care team members	Patient care team members	Patient care team members
	Delegation of responsibility	Predefined	On the spot	Predefined
	Delegation of tasks	Predefined	On the spot	Predefined
	Delay tolerance	Unknown	None	None
	Outcome type known in advance	Yes	No	Yes

Sørby et al. (2005) found that when the IPO model was applied to some scenarios the mobile EPR was found to be beneficial in some situations such as when decisions and plans were a direct result of consulting formalised information from the EPR. The IPO model was found to serve as a constructive tool before and throughout system design.

3.2.4 Use of Semi Structured Interviews

Results from the MOBEL project suggested that observational studies can be a useful tool for requirements elicitation and analysis for both hospital information systems and a

large variety of complex sociotechnical systems. The preceding studies reviewed focused on observations, whereas Spetz, Burgess & Phibbs (2012) utilized semi structured interviews to analyse the implementation of a new IT technology. Spetz et al. investigated staff resistance to the implementation of new technologies. This study involved a qualitative analysis of the hospital-based information technology systems in the United States Department of Veterans Affairs (VA) hospitals. Participants included nurses, pharmacists, physicians, IT staff and management. The aim of the study was to identify the factors and strategies leading to the successful implementation of the IT system. Findings from Spetz, Burgess & Phibbs (2012) study suggested that successful implementation was based on four factors;

1. Support for the new system from staff and management
2. Development of a gradual and flexible implementation approach.
3. The required resources allocated for equipment and infrastructure,
4. The way in which the implementation team planned for complications and overcame these to realise their goals.

3.2.5 Usability Testing

A core feature of testing of new prototypes in software development is usability testing. Usability is defined broadly by ISO (2010) as the effectiveness, efficiency and satisfaction with which specified users achieve specified goals in particular environments. According to Nielsen (2000) the usability of a web site can be evaluated through the use of usability heuristics, walkthroughs and usability testing with users. Exercises such as thinking aloud, questionnaires, and interviews are common in usability testing. The Human-Centred Design (HCD) approach to the development of software detailed by ISO (2010) is concerned with making systems usable and useful by concentrating on the users, their needs and requirements, applying ergonomics, and usability knowledge and techniques. This approach enhances effectiveness, efficiency, improves human well-being, user satisfaction, accessibility and sustainability; and limits possible adverse effects of use on human health, security and performance. The HCD approach complements existing systems design approaches and can be incorporated as

part of the waterfall model of software development. Koivunen & May (2002) detailed some common web usability problems including:

- **Structure:** providing a coherent and effective structure that supports tasks
- **Navigation:** providing the user with context keys (Where am I? Where did I come from? Where can I go to?)
- **Consistency**: Using design templates for layout, demonstration and interaction of distinct pages
- **Feedback:** Emphasizing important information, providing feedback about user actions
- **Searchability:** Supporting effective search, providing context of the site on any page through use of metadata
- **Control and Safety:** Optimising user control while providing constraints that reduce errors and service user confusion.

3.2.6 Poorly specified eHealth Interventions

eHealth interventions that are inadequate are less likely to be adopted by healthcare professionals and run the risk of implementation failure. Studies by Catwell & Sheikh (2009) stress the importance that eHealth interventions be "fit for purpose" and appropriately specified. Poor requirements specification can lead to eHealth projects having functional errors, being unreliable and not user-friendly (Catwell & Sheikh, 2009). Additional requirements issues reported include poorly prepared or supported context which can be dangerous to the service user and health service.

3.2.7 Context, Mechanism and Output configurations

The Context, Mechanism and Output configurations (CMOc) suggested by Pawson & Tilly (1997) espouses contextual thinking to investigate for whom and under what circumstances a programme or intervention will work. A mechanism does not refer to the specific component part of an intervention such as pre or post testing. Mechanism refers to the ways in which any one of the intervention components or any set of them, or any phase or set of phases brings about change. An intervention can be analysed, explained and developed through mechanisms. Mechanisms elucidate the reasoning of users by highlighting the resources made available to the participants (Pawson & Tilly,

1997). Mechanisms activated by an intervention will vary according to different conditions as programmes are almost always introduced into more than one context. Pawson and Tilly contend that the real power of a programme is in its ability to access existing resources and reasoning in specific contexts. Figure 8 amended from Pawson & Tilley's (1997) seminal Realistic Evaluation would suggest that by using a mechanism such as In-MINDD we can hope to produce a change in regularity (in individuals' cognitive health) in a particular context such as primary care. The outcome is then the change in regularity following the introduction of a social change program. In this framework evaluations of social programmes are concerned with how regularities are altered.
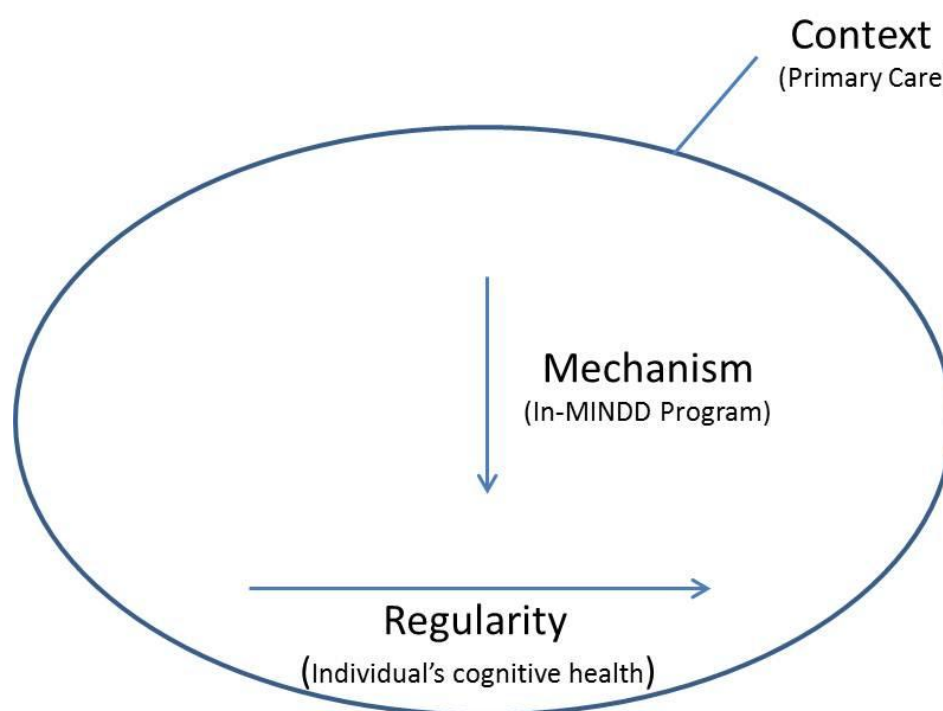
Figure 8: Pawson & Tilley 1997. Context, Mechanism & Regularity

As a result of the multiple contexts and mechanisms activated, every programme is likely to have a mixture of outcome patterns. Pawson and Tilley contend that evaluation studies produce context mechanism outcome configurations (CMOc). The CMOc then encapsulates the relationships between the context mechanism and outcome in realist

terms. The CMOc can then be used to develop transferable research findings crucial for policy development.

Contemporary eHealth initiatives are commonly beset by two types of difficulties; process problems and structural problems (Murray et al., 2010). Process problems relate to implementation of new ways of thinking, acting or organising care delivery mechanisms. Structural problems relate to the integration of new systems of practise into existing organisational and professional setting. Normalization Process Theory (Murray et al., 2010) is an explanatory model that can be used to understand the process and structural issues that lead to innovations becoming embedded into routine work.

3.2.8 Normalization Process Theory

On review of the literature on this topic a number of approaches to information processing of data elicited from requirements elicitation methods such as IPO and CMOc were identified. An engagement focused approach matching core requirements for this study was Normalisation Process Theory (NPT) as described by May et al. (2010). NPT can be employed to identify factors that promote and restrict the routine incorporation of complex interventions into daily practice (Murray et al., 2010). The evidence suggests that a complex intervention is more likely to have a significant impact on healthcare outcomes if it is observed to be effective when tested. Murray et al. concluded that such interventions are more likely to be implemented and become normalised into routine practice. Bridging the information gap between requirements elicitation research and the implementation of human factors in health-care interventions is a modern challenge. NPT as described by May et al. (2010) identifies a number of social factors needed to successfully implement and integrate interventions into routine work (normalisation). NPT explains how complex health interventions function, considering early implementation and beyond to the point where an intervention progresses completely embedding into routine practice. For the In-MINDD tool requirements development NPT is useful to investigate the barriers and facilitators to clinical engagement. Figure 9 presents the four central components to NPT as related by

Mair et al. (2012): coherence (or sense-making); cognitive participation (or buy in); collective action (work done to enable the intervention to happen); and reflexive monitoring (formal and informal appraisal of the benefits and costs of the intervention). These components are not linear, but are in dynamic relationships with each other and with the wider context of an intervention, such as organisational context, structures, social norms, group processes and conventions. May et al. (2010) describes coherence as the way in which a team or individual makes sense or operationalizes some new set of practices. Cognitive participation or engagement as detailed by May et al. (2010) investigates the work undertaken with potential users and get them to embrace the new e-health system.

Coherence (Sense-making work)	Cognitive participation (Relationship work)	Collective action (Enacting work)	Reflexive monitoring (Appraisal work)
Differentiation Is there a clear understanding of how a new e-health service differs from existing practice?	**Enrolment** Do individuals "buy into" the idea of the e-health service?	**Skill set workability** How does the innovation affect roles and responsibilities or training needs?	**Reconfiguration** Do individuals try to alter the new service?
Communal specification Do individuals have a shared understanding of the aims, objectives and expected benefits of the e-health service?	**Activation** Can individuals sustain involvement?	**Contextual Integration** Is there organizational support?	**Communal appraisal** How do groups judge the value of the e-health service?
Individual specification Do individuals have a clear understanding of their specific tasks and responsibilities in the implementation of an e-health service?	**Initiation** Are key individuals willing to drive the implementation?	**Interactional workability** Does the e-health service make people's work easier?	**Individual appraisal** How do individuals appraise the effects on them and their work environment?
Internalization Do individuals understand the value, benefits and importance of the e-health service?	**Legitimation** Do individuals believe it is right for them to be involved?	**Relational integration** Do individuals have confidence in the new system?	**Systematization** How are benefits or problems identified or measured?

Figure 9: Mair et al. (2012) Normalization process theory coding framework used for qualitative analysis of review data on e-health implementation.

May et al. (2010) contend that low coherence, cognitive participation, collective participation and reflexive monitoring can lead to reduced chances of successful implementation for a new eHealth intervention. An example of this could be low coherence among healthcare providers, where there is poor understanding of the need for an intervention negatively impacting implementation. In another instance buy in may be achieved from GPs but there could be a lack of resources or skills (low collective

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action) which could also have a negative impact on implementation. In the instance of this research NPT was utilized to elicit requirements that serve to enhance coherence, buy in, collective action and reflexive monitoring.

Mair et al. (2012) conducted a systematic review of the literature relating to the implementation of e-health systems. The review of e-health implementation studies focused on implementation processes, critical appraisal and evaluation of methodology and synthesising results. NPT was utilized in order to interpret the results. The objective of this review was to investigate the barriers and facilitators to eHealth implementation. Mair et al. suggested that in contrast to the increased uptake of information and communications technologies among health officials and policy makers, in practice uptake and utilization of e-health systems was poor. This finding is consistent with the European Union (Watson, 2010) implementation of e-health "has almost everywhere proven to be much more complex and time-consuming than initially anticipated."

3.2.9 Clinical Engagement through Normalization Process Theory

A search of the CINAHL database for articles including the terms "normalization process theory" and "requirements" produced six results. None of the articles indicted the use of normalization theory to guide engagement processes for requirements development. McEvoy et al. (2014) conducted a systematic review of 29 articles 3 of which reported the use of NPT to inform the development of tools that support implementation work. However, of the 3 studies none used NPT as a tool to guide requirements development or to specifically structure requirements gathering questions. As such this indicates a gap in the knowledge base for the use of the NPT framework to structure data gathering questions at an early stage. Furthermore, McEvoy et al. found an over emphasis of studies investigating single stakeholder perspectives rather than multiple stakeholder perspectives. Service providers rather than service users were studied indicating a need for the inclusion of multiple stakeholder perspectives in future studies. The under representation of the service user perspective is worthy of note for new research investigating engagement process in requirements development.

3.2.10 Workarounds

Kawamoto, Houlihan, Balas, & Lobach (2005) conducted a systematic review of 70 randomised control trials to identify features of clinical decision support systems critical for improving clinical practice. Four features were found to be strongly associated with the ability of a decision support system to benefit clinical practice; (a) decision support provided automatically within clinician workflow, (b) decision support delivered at the time and location of decision making, (c) actionable recommendations provided, and (d) computer based. Where the clinical decision support system is dependent on clinician initiative for use Kawamoto et al. (2005) recommends monitoring and taking precautions to ensure that clinicians access the resource as intended. Kawamoto et al. explain that in general an effective clinical decision support system must reduce the effort required by primary healthcare staff to receive and act on system recommendations. For instance, automatically providing decision support eliminates the need for clinicians to pursue system advice, and the use of a computer system enhances the consistency and reliability of the clinical decision support system by reducing labour intensive and error prone processes such as manual chart calculations. This illustrates the importance of minimising the cognitive load on the clinician. Furthermore it highlights how implementation can be undermined by the contending priorities of system users. When decision support systems make life difficult for the clinician, physicians have been known to use workarounds to avoid data entry (Ash, Sittig, Campbell, Guappone & Dykstra, 2007).

3.3: **Research Aims**

This Chapter detailed the need for sufficient clinical engagement during requirements development for the In-MINDD tool in order to enhance chances of successful implementation. A number of different approaches to information processing, data gathering methods and clinical engagement processes as part of the requirements development process were reviewed and critiqued. This Chapter appraised the literature on the differing approaches to software and requirements development focusing on aspects of Human Centred Design, Service User involvement, Normalisation Process Theory and Usability Testing. The focus of this research is on gathering requirements for the In-MINDD tool so that it can complement the existing technology systems and achieve optimal clinical engagement. Given the expected benefits of Personal Health Records to enhance self-care management of dementia risk and protective factors, the known barriers and facilitators to eHealth interventions implementation and the impact of clinical engagement the following research aims were created;

1. To gain a deeper understanding of the context into which the In-MINDD tool will be implemented and to illustrate this context to key stakeholders engaged with the process of In-MINDD tool design and development.

2. To understand the conditions facilitating the development of user requirements needed to build a personal healthcare record namely the In-MINDD tool from the perspective of two roles namely (a) the healthcare professional and (b) the service user.

3. To explore clinical engagement processes with stakeholders used to elicit requirements.

4. To investigate the most appropriate way to optimise clinical engagement processes with GPs and service users.

5. To optimise the social and technical "fit" between the In-MINDD tool and the existing primary healthcare domain for sustainable impact.

Chapter 4: Methodology

4.1: Overview

4.1.1 <u>Introduction</u>

In order to develop a methodology it was appropriate to choose a theoretical framework to underpin the research. The previous chapters have detailed the consideration of a very complex and context dependent situation. Thus a theoretic lens that allowed for such breadth and flexibility was fundamental. The purpose of this chapter is to develop a methodological approach to best address the identified aims of this study. The merits and flaws of a number of theoretical frameworks are discussed. Each framework would provide a different prism with which to address the research question and research aims. Sound reasoning is provided for the choice of critical realism as a theoretical framework and case study as a methodology used to investigate requirements development for the In-MINDD tool.

4.1.2 <u>Research Paradigm</u>

A research paradigm is comprised of an ontology, epistemology and methodology (Anderson, 2013). Anderson (2013) describes an ontology being a way of constructing reality, epistemology being the different forms of knowledge of that reality and methodology being the tools that the researcher uses to investigate that reality. In the case of this particular study the manner in which engagement with the requirements development process for a new PHR intervention was investigated was shaped by the theoretical framework to which the researcher adhered. In cases where a framework is not explicitly chosen or acknowledged it is noted that this can lead to problems with methodology and with analysing research findings (Alderson, 1998). Following consideration of a number of frameworks a critical realist framework was deemed most appropriate and a case study methodology was adopted. The analytical strategy used to scrutinise case study findings involved relying on theoretical propositions as described by Yin (2003) further expanded in Section 5.4 p. 71. The analytical strategy was complemented by the use of two core descriptive frameworks Context, Mechanism, Output Configurations (CMOc) as related by Pawson & Tilley (1997) and Normalization Process Theory framework as detailed by May et al. (2010) and discussed previously in Chapter 3.2.7 and 3.2.8.

4.2: **Theoretical Frameworks**

Theoretical frameworks are used widely in research. By explicitly stating and adhering to a theoretical framework Alderson (1998) asserts that new insights can be discovered and elucidated. The three types of theoretical frameworks discussed here include positivism, social constructivism and critical realism.

4.2.1 Positivism

Positivism is an outdated approach influential in the mid-nineteenth century that was concerned fundamentally with constant, replicable facts or units of knowledge (Robson, 2002). The positivist believed that knowledge gained from direct experience or observation is paramount to research. Intangible or theoretical entities were precluded from attention and the existence of an external reality denied (Robson, 2002). Positivism was very much concerned with cause and effect leaving little room for individual or intangible differences. The positivist approach is widely discredited today but was extremely influential particularly in quantitative research. The elicitation of requirements for a new eHealth intervention requires a qualitative, nuanced and pragmatic framework taking data from context, stakeholders and mechanisms into account.

4.2.2 Social Constructivism

In contrast to positivism, social constructivism concludes that there is no absolute truth or perspective and that a range of perspectives can be valid in different circumstances or at different times (Alderson, 19998). Rather than treating facts as strictly knowable objects social construction suggests   that people construct their reality through their joint experience and interaction with others. According to Alderson (1998) attempts to promote a healthier lifestyle, are more likely to succeed when the social context is understood as a complex, multifaceted combination of many interrelated factors rather than a set of disparate variables. Social constructivism theories in healthcare often focus on the relationships between researchers/practitioners and service users. Spoken words and body language during interaction are examined for how they symbolise larger issues, such as the way doctors maintain their professional status (Alderson, 1998). Alvesson and Skoldberg (2009) criticize social constructivism as preoccupied with the

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investigation of the construction of reality dismissing the role of mechanisms. For critical realists the concept of "mechanism" used interchangeably with "process" is central to explanation, and these mechanisms and processes are seen as real phenomena, rather than abstract models (Maxwell, 2012).

4.2.3 Critical Realist view of Causality

Critical realism is a prominent theoretical framework in qualitative research particularly in the field of program evaluation made famous by (Pawson & Tilley, 1997). According to Pawson & Tilley the relationship between causal mechanisms is dependent on the context within which the mechanism operates:

> "The relationship between causal mechanisms and their effects is not fixed, but contingent" (p. 69);

Critical realism is opposed to the social constructivism standpoint that multiple realities are constructed by different individuals. However, critical realism is compatible with the idea that there are different valid perspectives on one knowable reality (Maxwell, 2012). Knowledge, according to Alvesson and Skoldberg (2009), is always framed by theories and we cannot investigate anything without the help of theories. Reflection over theories, and the ensuing development of them, in order to provide deeper understanding of what is under study, is an integrating part of research. The most appropriate framework reviewed with relation to the requirements elicitation for a new eHealth intervention for self-care management was deemed to be a critical realist approach.

Critical realism can be a pragmatic choice for those doing social research (Robson, 2002). Roy Bhaskar originated the theory in the 1970's. Critical realism seeks to identify those deeper lying mechanisms which are taken to generate empirical phenomena (Alvesson and Skoldberg, 2009). Critical realism is concerned with the underlying mechanisms and structures that support phenomena with a view to understanding or creating theoretical insights. Bhaskar describes this as a shift from epistemology to ontology, and within ontology, as a shift from events to mechanisms (Alvesson and Skoldberg, 2009). Robson (2002) contends that context must be understood by the critical realist experimenter in order to develop theories for future

investigation in addition to understanding about a particular mechanism. Understanding the mechanisms at work and contexts into which they sit provides a theoretical understanding of what is going on which can then be used to optimize the effects of the innovation by appropriate contextual changes or by finding alternative ways of countering blocking mechanisms, thereby changing the innovation itself so that it is more in tune with the context where positive change has not been achieved (Robson, 2002).

According to Mingers, Mutch & Willcocks (2013) critical realism supports realist ontology that the world exists independent of our knowledge of it. It defends this standpoint in contrast to classical positivism and social constructivism discussed above. From an informatics perspective a general description of ontology is a formal specification of the terms in a target domain and the definition of the relations between these concepts (Noy & McGuinness, 2001). A formal specification for In-MINDD concept must take into account the anxiety and fear that a new eHealth initiative may cause for service users. By conducting research that helps to build user requirements for the In-MINDD tool some conceptualizations may be reframed.

Critical realism asserts that real world research is restricted and always facilitated by one's perceptual and theoretical frameworks. Critical realism accepts that knowledge is always local and historical, but does not accept that all perspectives are similarly valid. For instance the perspective of a key stakeholder such as a GP may be more important than another less important stakeholder; ultimately this is decided by the researcher in conjunction with the research team and program developers. This is important in the context of this particular study where many different stake holder opinions and attitudes were collected coming from a wide range of different backgrounds. Each perspective will have variable levels of importance to the research. Within this framework different types of units of knowledge such as physical, social, and conceptual are acknowledged as having different ontological and epistemological features. They therefore require a range of different research methods and methodologies to access them. Since a particular object of research may well have different characteristics, Mingers, Mutch & Willcocks (2013) suggest the use of a number of different research methods as required.

4.2.4 <u>Realistic Evaluation</u>

From a Critical Realist (Pawson & Tilley, 1997) perspective boundaries are not set.
Action mechanisms are investigated through research methods to understand why an
intervention works or does not under what circumstances and for whom. In this way one
may return to the intervention to make changes making it a more attuned intervention to
its context. The In-MINDD concept endeavours to set up a framework for sustainable
future research. Therefore this approach seeks to contribute to a sustainable future
version of the In-MINDD tool. It is not the aim of this Chapter to develop hypotheses in
order to test existing theories, but to provide a grounded basis from which empirical and
practical investigations on the requirements elicitation for the co-design phase of the In-
MINDD tool. Clark, Lissel & Davis (2008) contend that when Critical Realism is
applied to research it can be useful for optimizing interventions. Critical realism has
been influential in the sphere of program evaluation. Many realist evaluation studies
have utilized the case study methodology to investigate interventions in complex
settings (Marchal, Dedzo & Kegels, 2010). Bearing this in mind critical realism is
adopted as an appropriate framework for the current research and appropriate
methodologies are now discussed.

4.3: **Design Strategy**

In order to choose an appropriate methodology to investigate this topic a number of
different design strategies were considered. Robson, (2002) provides insight as to when
it is appropriate to use either a flexible or fixed design strategy. According to Robson a
fixed design is justified by a tight pre-specification before one reaches the main data
collection stage and data collected is usually quantitative. As the requirements
development process was not pre-specified before the data collection stage of this
research a flexible design strategy was deemed most appropriate. A flexible design
evolves during data collection and data collected is typically qualitative. Robson
recommends that if the focus of a study is on evaluating a process a flexible design is
probably most applicable. Some different flexible designs considered included an
ethnographic study, a grounded theory study and a case study. Ethnographic studies

originate in anthropology and focus on describing and interpreting a cultural or social group. Grounded theory studies stem from sociology and focus on developing a theory grounded in data from the field. Case Study research originates from social sciences, sociology, political sciences and importantly evaluations studies and focus on developing an in depth analysis of a single or multiple case or cases (Robson, 2002).

4.4: **Case Study**

The case study methodology was deemed most appropriate. Two eminent authors on Case Study research reviewed to inform the methodology include Robert Yin (2003) and Robert Stake (1995). Yin (2003, p.42-43) describes when it is appropriate to use a case study methodology: to test a well-formulated theory, to investigate a unique or extreme case, when tasked with an extraordinary opportunity to study a phenomenon, or finally investigating a longitudinal case. Multiple case designs can be used for comparing different instances of the same phenomenon.

The case study as a method allows researchers to understand complex social phenomena (Yin, 2003). The focus of this research was to complete requirements elicitation for optimisation and successful deployment of the In-MINDD tool for individuals wishing to engage with a cognitive health self-care management PHR initiative. This presented an opportunity to study what Yin would call both a unique case and complex social phenomena. The health message In-MINDD is promoting is complex combining a number of dementia related risk, protective and manageable health and social factors. In-MINDD is aimed at four different EU countries with three different languages involving confidential health data. The case study methodology provides scope to investigate the holistic and meaningful characteristics of the software development lifecycle of the design, testing and implementation of the In-MINDD tool.

Stake (1995) contends that the case study provides the researcher opportunity to investigate the particularity and complexity of a single case. Findings can be transferred from context to context as opposed to generalized. In later studies Stake concedes that qualitative research can contribute to stereotyping but that for the most part it defends against it. He suggests a more comprehensive understanding is reached through case study research highlighting the investigation of particular case history, stakeholder

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experiences, dialogue, multiple contexts, research methods, activities, issues and questions.

In order to carry out a successful case study Yin (2003) suggests the following components; use of multiple sources of evidence, use of a case study database and a chain of evidence. A chain of evidence can provide a researcher with defined links that can be observed to help the researcher make sense of data collected leading to the conclusions drawn. Crabtree & Miller (1999) have conducted research on primary care settings and suggest that the interview technique should use multiple sources, ask "how" questions as opposed to "why" questions, not be dependent on one source of evidence and not to become over friendly with any interview participant as this can lead to bias.

4.4.1 <u>Issue Questions</u>

As a case is a bounded social system (Stake, 2014), it is important to investigate its individual parts. According to Stake, a system is an assemblage of interacting things or parts into a functioning whole. Systems can be social having functions and purposes. A bounded system has spaces, territories, with recognizable edges between inside and outside, with different functions occurring in different spaces. Some examples of bounded systems include an organization, a program, a family, a school class or a person. In order to provide structure for case studies Stake (1995) suggests the use of issue questions to bound or reduce the space of the case. An issue itself is worthy of study but it is studied in a case and discussed in the case study report because it helps one to understand the phenomena under investigation. Issues identified provide a way of breaking down the case into sections for deeper analysis. In order to choose whether or not an issue is worth researching Stake (2014) proposes some issue questions for the researcher to ask provided here in Table 3, amended with questions the author asked when considering if the issue was worth pursuing.

Table 3: Issue Questions for the Case Study Researcher based on (Stake 2014) with additions by the author.

Issue Questions for the Case Study Researcher	
Case Study based on Stake 2014	Requirements Analysis
1. Is this issue relevant to this particular case? Might inquiring about the issue help us understand the case?	1. Might inquiring about this issue lead to defined requirements?
2. Is there tension? Are at least two value positions present? Are there differences in opinion? Is it being argued? Even if it isn't being talked about, if it were, would there be disagreement?	2. Is there tension between GP and Service user requirements? Could this lead to poor uptake and subsequent use of the in-MINDD tool?
3. Is the issue important to those in the case? Does anyone care?	3. Are the issue(s) important to the stakeholders involved? Which stakeholders find the issues most important. Who engages most readily with the issues under study most readily?
4. Will it be useful to study the issue?	4. Why should we study this issue? Will there be implications for requirements development? Will there be implications for engagement processes?
5. Does it have educational implications?	5. Will there be training implications for Healthcare Professionals (HCP) and Service Users.

The case study as a methodology has been attacked for not having sufficient academic integrity, lacking accuracy, objectivity, and discipline (Yin, 2003). These criticisms seem to stem from the fact that case study can be used as a teaching tool or a journalistic tool and as such has earned a bad reputation. When employed scrupulously it is as valid as any other methodology (Yin, 2003). The aim of this case study research was to investigate clinical engagement processes as part of the requirements elicitation process for the In-MINDD tool in all its particularity. Findings were valued for the insights they

can provide to this particular project as opposed to how findings can be generalized. By exploring the multiple facets of clinical engagement during requirements development it was hoped to gain a more full understanding of the research question and research aims related in Chapter 5.1 p. 64.

4.4.2 Summary

This chapter discussed the role of critical realism as a theoretical framework adopted. As critical realism can be useful for optimizing interventions (Clark et al., 2008) it is appropriate as a theoretical framework to underpin this research. Case study provides a methodology which can be utilized to investigate the dynamics of the clinical engagement processes occurring in a specific context (primary healthcare) with the specific case being the In-MINDD tool. The case study methodology allows for the full particularity of the clinical engagement during the requirements development process for the In-MINDD tool to be analysed. Reasons for choosing case study include its appropriateness for investigating interventions in complex settings (Marchal, Dedzo & Kegels, 2010) and the emphasis that is placed on stakeholder experiences, multiple contexts, issues and questions. The purpose of the next Chapter is to analyse the research design formed to study clinical engagement processes within the requirements development process. The next chapter describes case selection, ethical approval, data collection methods and materials and the data analysis methods used.

Chapter 5: Research Design

5.1: Overview

5.1.1 Introduction

Chapter 4 detailed and gave critical account of the selection of case study as a methodology underpinned by the critical realist paradigm as a theoretical framework.

The purpose of this Chapter is to analyse the research design. A research design was formed in order to select an appropriate case, collect and analyse data in a rigorous way and create a chain of evidence with which to confirm consistency of findings. In order to adequately justify and credibly defend research queries and objectives within a particular research design Clark et al. (2008) contend that the researcher should critically analyse the choices made. In addition, the research design can link specific criteria such as Stake's (2014) issue questions to the research queries (Bryman, 2004, p.27). The researcher followed guidelines set out by Stake (2014, p.9) to create research queries described in Table 4, by first asking issue questions proposed by Stake the researcher was able to form similar questions from the perspective of requirements elicitation for the In-MINDD tool. Table 4 indicates the formulation of research queries guided by Stake's (2014) criteria.

Table 4: Formulation of Case Study Question and Research Queries

Queries for the Case Study Researcher			
Case Study Issues	Requirements Analysis	Example Issue	Research Queries
1. Is this issue relevant to this particular case? Might inquiring about the issue help us understand the case?	1. Might inquiring about this issue lead to defined requirements?	Participant Data How do we recruit the population of interest?	2. What are the key types of data that are currently collected by GPs on service users within their practice?
2. Is there tension? Are at least two value positions present? Are there differences in opinion? Is it being argued? Even if it isn't being talked about, if it were, would there be disagreement?	2. Is there tension between GP and Service user requirements? Could this lead to poor uptake and subsequent use of the in-MINDD tool?	Clinical Engagement How do you optimise stake holder engagement with the program?	1.What is the potential context of use for the In-MINDD tool?
3. Is it important to those in the case? Does anyone care?	3. What are the barriers to stakeholder engagement? What are the benefits of the In-MINDD tool to the stakeholder? What are the disadvantages of the In-MINDD tool to the stakeholder?	How do we evaluate success?	5. Does the end prototype tool meet the study requirements elicited from key stakeholders?
4. Will it be useful to study the issue?	4. What factors could mitigate the barriers and enhance the benefits. What factors could aggravate the barriers and diminish the benefits.	What structures need to be in place to optimise end user engagement with the program?	3. Considering the NPT Constructs what barriers and facilitators have the potential to impact on successful deployment of the In-MINDD tool?
5. Does it have educational implications?	5.Will GPs have the time to engage with requirements research?	Will HCPs or service users need training or assistance?	4. What are the educational and training implications for stakeholders?

The literature reviewed informed the formulation of an overarching research question, research queries and research aims used to guide the line of inquiry and the research aims uses to structure discussion of findings. The case study was conducted with a view to investigating the following **research question**:

Research Question: *What are the current user and non-functional requirements in regard to self-care management and prevention strategies in relation to dementia risk and protective factors?*

In order to fully examine this question the following **research queries** guided the line of inquiry:

1. *What is the potential context of use for the In-MINDD tool?*
2. *What are the key types of data that are currently collected by GPs on service users within their practice?*
3. *Considering the NPT Constructs what* barriers and facilitators *have the potential to impact on successful deployment of the In-MINDD tool?*
4. *What are the educational and training implications for stakeholders?*
5. *Does the end prototype tool meet the study requirements elicited from key stakeholders?*

The **research aims** for this case study are:

1. To gain a deeper understanding of the context into which the In-MINDD tool will be implemented and to illustrate this context to key stakeholders engaged with the process of In-MINDD tool design and development.
2. To understand the conditions facilitating the development of user requirements needed to build a personal healthcare record namely the In-MINDD tool from the perspective of two roles namely (a) the healthcare professional and (b) the service user.
3. To explore clinical engagement processes with stakeholders used to elicit requirements.
4. To investigate the most appropriate way to optimise clinical engagement processes with GPs and service users.
5. To optimise the social and technical "fit" between the In-MINDD tool and the existing primary healthcare domain for sustainable impact.

5.2: **Selection of Case**

Stake (2014) proposes that case study research is not sampling research. Generalizability of findings to other cases is not of paramount importance. According to Stake the first criterion of case selection should be to increase our knowledge of a particular case. It is therefore necessary to describe the case selection process adopted for this study. As previous elaborated in more detail in Chapter 4.4, case selection is the suitable selection of one or more instances of the phenomenon under investigation by the case study researcher. In order to choose an appropriate case one must consider which cases are most relevant to the research question and are likely to lead to insights, assertions and even modification of generalizations (Stake, 1995). As time constraints and access in the field is always limited Stake (1995) suggests selecting cases which are easy to access and open to inquiry, with some identifiable actors who may be willing to review draft materials. Cases should be identified for providing the most robust information on the program under study.

A number of approaches were considered and following supervisory meetings the In-MINDD tool was selected as the case for study. The choice of the In-MINDD tool as the case for study provided a number of options to the researcher. One of these options was a strong focus on defining the systems requirements for optimum service delivery. Potential participants could therefore be defined as any stakeholders who would interact with the In-MINDD program or any stakeholders who could provide insight into contexts, processes, mechanisms, relevant to the development and implementation of the In-MIDD program. This allowed for the uniqueness of this case to be investigated from a number of stakeholder perspectives and contexts.

5.2.1 <u>Research Ethics Committee Approval</u>

Ethical approval for the current study was obtained from the Dublin City University (DCU) Research Ethics Committee (REC). The ethics application was prepared by the researcher, under the guidance of PhD supervisors. Permission was sought to interview and carry out focus groups with identified stakeholders meeting an eligibility criteria. Stakeholders included GPs practicing for 12 months and their service users aged between 40 and 60 years old with at least one of the dementia related risk factors. The

application was submitted to the DCU REC on 31.05.13 and approval was granted on 02.07.13.

5.3: **Data Collection and Materials**

This section describes the data collection methods, materials and protocols used within the study. Data were collected in order to define the case, answer the research queries and aims, identify stakeholders, get to know stakeholders, identify problems for stakeholders and to identify data sources. Stake (1995) urges the researcher to take early opportunity to get to know the people, the spaces, the schedule and the problems of the case. It is also important in case study to compare the strengths and weaknesses of differing data collection research approaches. For example audio and or videotape, can provide rich data. Time and ethical demands can however be prohibitive. Audio taping is valuable for capturing the exact words or phrases but there is a cost in the time spent transcribing. In the case of the current research videotaping was not required however audiotaping was found useful for interviews, focus groups and usability testing.

A number of data gathering methods were considered. The method selected as most appropriate to the study depended on a range of factors including the focus of the study, the participants involved and the resources available. The four qualitative research methods considered were observations, interviews, focus groups and usability testing see Table 5. These methods are discussed further below and the rationale for the choice of method is presented.

Table 5: Considered Research Methods

Methodology	Aim
Observations	Exploring context of user activity
Interviews	Investigating issues
Focus groups	Collecting various perspectives
Usability Testing	Gain new perspectives on a product

In the case of new technologies, observations can be an invaluable aid for understanding the actual uses of the technology or potential problems being encountered. According to Yin (2003) an observational protocol is comprised of measuring a specific behaviour during defined periods of time in a specified place. Observations can be enhanced by taking photographs, filming or having more than one observer. Initial research suggested that primary care centres would be used as case sites for research. It was anticipated that observations were to be carried out in each primary care centre taking part in the research. An observational protocol would have involved measuring the incidences of certain types of behaviours during certain periods of time in the field and involved observing meetings, GP software usage, and primary care team interactions. Due to restricted access to primary healthcare centres and a need for increased service user control the focus of the study switched to local GP practices for recruitment with service users as the core user. This increased the importance of the service user perspective over the course of the research. Local GP practices are generally smaller than primary healthcare centres not having the numbers of team members necessary to facilitate observations of team meetings as a result it was considered inappropriate to conduct observations. Following attempts to approach Public Health centres by phone the decision was made to approach local GP practices. Local GP practices were more amenable to participate with the research.

Semi-structured interviews were chosen as the more applicable method for requirements elicitation with GP stakeholders as very specific questions were being asked. Focus groups were considered appropriate for investigating service user perspectives. Finally usability testing was chosen to test and iteratively evaluate prototypes with service users. The following section describes the research methods, materials and protocols used to conduct the case study.

5.3.1 Semi-Structured Interviews

Semi structured interviews are any person-to-person interaction between two or more people with a specific purpose. Semi structured interviews involving a mixture of open and closed questions (Robson, 2002) were conducted with representative stakeholders and GPs discussed in Chapter 6. Stakeholders were identified and purposefully recruited by letter (see Appendix A), phone call or in face-to-face meetings for their expertise and knowledge in their field to identify core requirements for the In-MINDD tool. Robson (2002) describes purposive sampling as that which allows a researcher to judge whether a particular population are of interest and allows the researcher to satisfy the specific needs of a project. Analysis of stakeholder meetings is available in Chapter 6.

5.3.2 GP Interview Protocol

A number of data collection instruments were used to carry out the qualitative interviews with General Practitioners. GP interviews were at a context level and copies of the collection instruments are shown in Appendices B-E.

- Recruitment Letter (Appendix B)
- Information Sheet (Appendix C)
- Consent Form (Appendix D)
- Topic Schedule (Appendix E)

The questions chosen for interview, focus groups and usability testing were created to explore the specific research aims related in Section 5.1, p. 64.

5.3.3 Service User Focus Group Protocol

Focus groups are good for testing whether an idea behind an initiative (in this instance the In-MINDD tool) makes sense and if your value proposition (In-MINDD concept) is attractive. Krug (2006) recommends the use of focus groups early in the design process before a website is designed. This gave the researcher access to user opinions to test naming conventions for features of the site, identify issues and investigate service user opinions. For the purpose of this case study focus groups were used to investigate user

perspectives of the In-MINDD tool and concepts discussed at length in Chapter 7. In order to understand how well the In-MINDD tool worked and to improve it, usability testing was conducted. A number of data collection instruments were used to carry out the service user focus group interviews with case participants. Service user focus groups interviews were at a context level and copies of the collection instruments are shown in Appendix F-H.

- Information Sheet (Appendix F)
- Consent Form (Appendix G)
- In-MINDD Introductory Video see section see Section 7.5.5.
- Focus group Script (Appendix H)

Questions were developed using Krueger (1998a) sequence for developing questions whereby lead or open questions were asked followed by more focussed prompts. Analysis of service user focus groups is available in Chapter 7.

5.3.4 Usability Testing Protocol

Krug (2006) suggests usability testing should be carried out as early in the design process as possible. The process of usability testing includes a single user being shown a resource (website prototype, or some sketches of web pages) and asked to either (a) figure out what it is, or (b) try to use it to do a typical task. As Gould and Lewis (1983) observed usability testing should provide a user with simple tasks to complete and record their performance, thoughts and attitudes. The objective of usability testing is to gain new perspectives on a product and inform the judgement of the researcher on the merits and flaws of the prototype. Hayes et al. (2009) recommends that systems should also be piloted and evaluated from an un-biased perspective whereby the implementation of systems is not a foregone conclusion. The researcher followed Krug's (2006) guidelines for conducting usability tests. Data collection instruments used to carry out usability testing of iterations of the In-MINDD tool included a prepared usability test script (see Appendix I) based on a usability testing template by Krug.

5.3.5 RCT Qualitative Interviews

A feasibility report was written as a project deliverable to evaluate the effectiveness of the In-MINDD approach through the RCT previously described in Section 1.2.3. p. 5. The report concerns qualitative interviews conducted by the programme team with RCT participants from each partner country to evaluate the feasibility of the RCT approach. Relevant portions of the report have been analysed and reproduced in Chapter 8.5 to validate how well the In-MINDD tool incorporated user requirements gathered and to validate clinical engagement with stakeholders. The report is entitled: *D3.2 Evaluating the effectiveness of the In-MINDD profiler and on-line support environment: Feasibility randomised controlled trial.*

5.3.6 Ethical Concerns

A number of ethical concerns were associated with the research methods chosen, in particular those that related to confidentiality of participant information, anonymity and informed consent. Here the ethical concerns related to participant information are related.

Prior to taking part in research all participants received a participant information sheet. Strict anonymity of information was guaranteed to information disclosed in interviews, focus groups and usability test. Participants were assured that any information held on computer would be password protected and that any written notes would be stored securely in a locked filing cabinet and would not carry any information or identifying codes that connect individuals to specific recorded data. Participants were assured that information would only be available to the research team and that transcripts were to be anonymised. Consent forms detailed how personal identifying information would be held securely for a period of 10 years and that regulatory bodies auditing the conduct of the research would also have access to this information, for up to 5 years after the study had finished.Anonymised information would be archived and could be used in future research. Any identifying information was removed prior to quotes from interviews, focus groups and usability testing being used in academic research. GPs were further made aware that their GP practice would not be identifiable from the research. The

information sheet made participants aware that in exceptional circumstances for legal reasons it may be necessary to break confidentiality.

This section highlighted the suitability of the interview, focus group and usability testing in the context of the current research. The next section outlines the data analysis frameworks used to analyse data that was elicited with the aforementioned research methods.

5.4: **Data Analysis**

This section provides a plan for data analysis within the study. Data analysis involves categorising, tabulating and or recombining the data elicited from research methods to address the research aims. Yin (2003) and Miles and Huberman (1994) data analysis strategies were found useful to guide the researcher in terms of what to analyse and why. Miles and Huberman (1994) prescribe arranging arrays of information, placing information into matrices, creating flowcharts and graphics and arranging information in chronological order to facilitate the manipulation of data into a preliminary order. This process of "playing with the data" is recommended by Yin as a useful activity to help the researcher see patterns and emerging themes in the data.

5.4.1 Issue Questions

Yin suggests the strategy of *relying on theoretical propositions* as a suitable choice to guide case study data analysis. This strategy proposes following the theoretical propositions that have led to one's case study. The original objectives and design of the case study are based on the propositions, which reflect a set of research questions, queries, literature reviews and new propositions. These propositions or issue questions shaped the data collection plan and give priorities to the relevant analytical strategies. This is an example of the theoretical orientation guiding case study analysis. The propositions served to focus attention on relevant data and ignore irrelevant data. Furthermore the proposition or issue questions served to structure the case study and define the alternative explanations worthy of analysis.

In this study interviews, focus groups and usability tests were tape recorded and transcribed. In some instances the researcher took additional notes or a research assistant

was present to make notes. Transcripts were taken together with notes and in some instances In-MINDD project emails or meeting minutes and analysed by the researcher. As Yin (2003) proposes relying on theoretical propositions the researcher's aim was to answer research queries leading to the elicitation of user requirements by analysing case study data. In the case of the current research the guiding theoretical proposition was to conduct the requirements elicitation for the co-design of the In-MINDD tool with a view to gaining a deeper understanding of the system requirements for the In-MINDD tool. Such an approach ensures that the benefits of the system are aligned to the user needs and may increase integration of this system into the context when deployed. The causal relationships (how and why questions) investigated would include the case study issue questions. Some examples of these include;

How do you optimise stake holder engagement with the program? What structures need to be in place to optimise end user engagement with the program? How do we recruit the population of interest? How do we evaluate success?

Transcripts were analysed and important quotes were arranged by theme into interview notes. Interview notes were then analysed and arranged into user requirements by the researcher. Information gathered from initial interviews was used to develop class diagrams and use cases used to build and define context on the proposed look and feel of In-MINDD tool. This approach has been documented by Sørby, Melby, & Seland, (2005) and Dahl, Sørby & Nytrø (2004) as an effective method to complete a user centred design system requirements analysis.

5.4.2 <u>NPT & CMOc</u>

Following initial data analysis, relevant portions of transcript were further analysed using two core theoretical frameworks:

1. Normalization Process Theory as detailed by May et al. (2010)
2. Context, Mechanism, Output Configurations (CMOc) as related by Pawson & Tilley (1997).

A short summary of why these frameworks were considered appropriate is now related. The application of Normalisation Process Theory (May et al., 2010) can serve to uncover themes occurring within the wider context of the intervention, such as organisational context, structures, social norms, group processes and conventions. NPT is an explanatory model that can be used to understand the process and structural issues that lead to innovations becoming embedded into routine work. NPT constructs can serve to indicate which stakeholders buy into or engage with a programme and can be used to look at the reasons why engagement is achieved or not. The four NPT components: coherence, cognitive participation, collective action and reflexive monitoring were used to provide a structure for data collected from the research and to indicate which components were achieved with different stakeholders. Early service user engagement has been identified by Murray et al. (2010) as playing a key role in increasing the chances of successful implementation and integration of new eHealth systems. As illustrated in Chapter 3 Normalisation Process Theory (NPT) has been used to identify factors that promote and restrict the assimilation of complex interventions into daily practice (May et al., 2010). NPT was chosen as a toolkit to be used by the researcher to guide the requirements elicitation process for the In-MINDD system most importantly to investigate engagement with stakeholders and to identify factors that promote and restrict the incorporation of In-MINDD into everyday behaviour.

5.4.3 Data Triangulation

Case study research involves investigations of multiple data sources forming a chain of evidence. The case study researcher is tasked with checking and rechecking the consistency of findings across a number of different and similar sources. This process is known as triangulation. Triangulation involves the researcher examining findings from three sources or more to investigate if they all indicate the same conclusion. An example of triangulation from Yin (2003) is hearing the same findings echoed from different participants at different stages of research or with different methods. The two strategic tools available to the case study researcher to reach new knowledge include direct interpretation and categorical aggregation. Some instances are interpreted and related in the case study report for their importance of themselves, others become more important as their instances reappear.

5.5: **Summary**

This chapter described the research design created for this case study in order to elicit requirements for the In-MINDD tool. Reasoning behind the selection of the In-MINDD tool as the case under study was provided. Research methods identified with which to gather information on the case include interview, focus groups and usability testing. The data sources investigated by the researcher include a number of relevant stakeholders, GPsand service users. . This is addressed in more detail with relevant stakeholder interviews described and analysed in Chapter 6. Chapter 7 describes and analyses GP interviews and service user focus groups. Chapter 8 provides information on an evaluation of prototypes of the In-MINDD tool usability testing. These data sources provided a rich tapestry with which to triangulate data guided by issue questions.

The purpose of the following Chapters (6 to 8) is to present the findings of the case study where information gathered through research methods is analysed with the help of the NPT Framework as detailed by May et al. (2010).

Chapter 6: Information Gathering Knowledge, Process and Communications

6.1: Introduction

Chapters 6-8 of this thesis present the case study findings of the requirements gathering process for the In-MINDD tool. The purpose of the case study (as described in Section 5.1.1, p. 64) is to answer the research question:

What are the current user and non-functional requirements in regard to self-care management and prevention strategies in relation to dementia risk and protective factors?

The research was conducted in three phases for ease of reading each phase is allotted a findings chapter in the thesis. The three phases are mapped to Chapters 6, 7 & 8 offering an account of the exploration of the requirements gathering process undertaken as part of the co-design of the In-MINDD tool. The approach adopted was intended to accurately understand the context of use in order to capture the requirements to optimise development and integration of the In-MINDD tool thus increasing the chances of an effective implementation strategy. The methods used were based on the theoretical and empirical foundations presented in Chapters 4 and 5.

Some elements of the findings may take on narrative style taking some of the attributes of a story. Stake (1995) suggests that case study reporting is not storytelling, however, some selections of vignettes are told taking on the elements of stories: *"characters have a problem, the situation worsens, following some climactic or extraordinary effort, the problem is resolved"* (p. 127).

This Chapter describes the information gathering research carried out with identified stakeholders investigating stakeholder knowledge involved with the In-MINDD tool. The purpose of this chapter is to investigate the context into which the system was designed to sit and describes the key stakeholders or characters in this context. In the case of this study the stories are described as part of use case development and scenario builds to inform development and testing of the prototype. Information gathered from stakeholder meetings is presented in chronological order in an effort to convey how issue questions were constantly changing and the requirements were constantly evolving in a dynamic way building on iterative loops of analysis.

Findings were based on a chain of evidence (Yin, 2003) from; interviews, focus groups and usability tests related by the researcher to the In-MINDD team specifically the IT developers. The chain of evidence gathered by the researcher led to the production of two key outputs; the User Experience (UX) Specification document (Appendix J) the Requirement Specification (URS) document (Appendix K). Portions of both documents will be presented throughout the following chapters to provide examples of requirements gathered (see Section 6.4. page x and page y) and subsequent recommendations based on new knowledge are presented in the Discussion Chapter 9.

Section 1.3 described how functional requirements for the In-MINDD tool were inherited from a systematic review of documented risk and protective factors associated with dementia followed by a two round Delphi study prior to this research. Functional requirement data sets were detailed by the researcher and included in the URS related to alcohol consumption, physical activity, coronary heart disease, chronic kidney disease, diabetes, cholesterol, smoking, midlife obesity, midlife hypertension, diet, mood and cognitive activity. The core functional data sets and scoring algorithms were set outside the scope of this research. The purpose was therefore to elicit non-functional and user requirements previously explained in detail in section 3.16 and 3.1.7. These requirements were conveyed back to the IT development team at periodic intervals through email, telephone calls and regular meetings. The IT developers made changes as required adhering to parts of the agile methodology where requirements can and will change. Figure 10 provides a visual map of the Case Study research. The images are used as signposts throughout the chapters to help situate the reader.

Phase 1: Information Gathering	**Phase 2: Design in Process**	**Phase 3: Evaluation**
Purpose eHealth Landscape Analysis	Purpose Recruitment/Co-Design of In-MINDD tool	Purpose Evaluation
Methodological Approach Interviews	Methodological Approach GP Interviews & Service User Focus Groups	Methodological Approach Usability Testing
Deliverable User Experience Specification Requirements Specification	Deliverables Requirements Specification Camtasia Introduction Video File	Deliverables Usability Report

Figure 10: Case Study Phases Overview

6.2: **Phase 1 Information Gathering**

This chapter is an introduction to the In-MINDD case study and provides an account of the first phase of the research entitled: Context Setting the eHealth Landscape in Ireland see Figure 10. The purpose of this chapter is to describe, examine and interrogate the information gathering work done to provide a clear account of the service user landscape that In-MINDD would be implemented into. Phase 1 situates the In-MINDD tool in context by describing the characters and setting into which the tool was designed for use. Findings were used to refine requirements and to assist with the integration of the In-MINDD tool into service users' activities of daily living to promote improved cognitive health.

6.2.1 Research Queries

During this phase of the case study the most applicable research queries included;

- *What is the potential context of use for the In-MINDD tool?*
- *What are the key types of data that are currently collected by GPs on service users within their practice?*
- *Considering the NPT constructs what* barriers and facilitators *have the potential to impact on successful deployment of the In-MINDD tool?*
- *What are the educational and training implications for stakeholders?*

6.2.2 Issue Questions

With each phase of the research a number of *issue questions (*Stake 2014) described in Chapter 4.4.1 p. 57 were formulated (see Appendix L).The researcher utilized the NPT framework to inform the formation of issue questions to emphasise clinical engagement. This had the effect of guiding the line of inquiry to investigate clinical engagement. With each successive stakeholder meeting these issue questions were in turn addressed or added to. One can liken this process to an accordion expanding and contracting. In accordance with the case study methodology the researcher began with a small number of issue questions that expanded and contracted depending on the line of inquiry. Some questions were answered outright and some led to more questions or a different line of inquiry. Issue question answers were analysed leading to the production of non-

functional requirements available in Section 4 of the User Requirements Specification Document (Appendix K) which were fed by the researcher back to the In-MINDD team at programme meetings and via email. Issues investigated included high level processes, inputs, outputs, data-types, technical specifications. Findings from meetings and interviews were used to create a User Experience (UX) specification document detailing the service user registration process with the aid of Unified Modelling Language (UML) see Appendix J for examples.

6.3: **Context setting the eHealth Landscape in Ireland**

As previously stated in Chapter 2.3 (p18) carrying out sufficient requirements analysis has been evidenced to significantly improve the definition of system requirements and optimise implementation and integration of new eHealth interventions (Heath & Luff, 2000). In order to define sufficient requirements it was first deemed appropriate to take stock of the eHealth landscape in Ireland with regard to who the key players are. Key players identified included; the In-MINDD IT development team, general practitioners, primary health care centre practitioners, and relevant stakeholders from medical educational institutions. Secondly it was deemed necessary to review the context in which general practice software providers, eHealth software companies, General Practitioners (GPs) and service users exist and interact. This phase of the research had the purpose of defining the anticipated non-functional requirements for a selected sample of key players deemed appropriate to approach. These non-functional requirements were then accommodated in the In-MINDD tool. Furthermore the purpose here was to investigate cognitive health promotion and the types of strategies (if any) used by GPs to help service users improve their modifiable and manageable risk factors for dementia. Phase 1 of the research took place during the first eleven months of the project timeline see Table 6.

Table 6: Information Gathering Phase

2012		2013								
Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep
1	2	3	4	5	6	7	8	9	10	11

Core research processes at this time included acting as a liaison between the stakeholders and the In-MINDD IT development (DCU School of Computing) team and facilitating focussed discussions on key aspects of the programme that needed to be agreed upon for development of the prototype.

Stakeholders were contacted by letter (Appendix A), email and phone calls. Seven stakeholders were interviewed in six meetings between January and September 2013. Age was not collected and all stakeholders were male. Meetings were informal and conversational in tone guided by issue questions with the purpose of discovering contextual information related to the development and implementation of a new eHealth initiative concerned with risk and protective factors for dementia. Meetings were exploratory, guided by predetermined list of topics see Table 7. Findings and analysis from earlier meetings informed the discussion in subsequent meetings so that new topics, issues and requirements emerged in a dynamic and organic way.

Table 7: Phase 1 Meeting Topic Schedule

Stakeholder	Date	No. of Meetings	No. of stakeholders	Researcher(s)	Issue Questions
eHealth Company	Jan	1	2	K. Power	**eHealth Context in Ireland** Who are the main primary care practice management software providers in Ireland? Who are the key players in the eHealth arena in Ireland with regard to primary care? What are the most widely used practice management software providers in Ireland? What core requirements would GP services in Ireland want from the In-MINDD system? What similar products are currently available on the market? Should In-MINDD embed into the local practice management software or would they suggest it be provided separately?
Medical Educational Professionals	Jan/ Feb	3	3	K. Power, Dr K. Irving, Dr.P. Hussey	**Investigating approach to practice management software companies.** Who are the main primary care practice management software providers in Ireland? How do we approach primary care practice management software providers with a view to collaboration? What are the key types of data that are currently collected by GPs on service users within their practice? What are the current requirements and service user needs in regard to self-care and prevention strategies in relation to dementia? What is the best approach to GP recruitment?
In-MINDD ICT Development team	April	1	20	K. Power, In-MINDD project team, DCU School of Computing ICT Team	**In-MINDD Plenary Meeting** K. Power given the following tasks: Create a first impression of the user interface of the In-MINDD tool.

				Aid the design and development of the user interface. What specific questions do the ICT team need asked in stakeholder discussions? Clarity needed on user and non-functional requirements for prototype delivery.
Practice Management Software company	June	1	1	K. Power, Dr K. Irving, (Members of DCU School of Computing, ICT Development Team)	**Possible collaboration with practice management company** Should In-MINDD be embedded into the local practice management software or be provided separately? What service user information is collected in general practice? How is service user information stored? How do GPs prefer to contact service users? How would one create a custom investigation for the In-MINDD lifestyle for brain health risk and protective factors? What additional functionality and features are required
GP	Sept	1	1	Dr K. Irving & K. Power	**Data entry, service user recruitment** What do GPs know about the modifiable risk factors for Dementia? What specific concepts and terms relating to dementia risk factors are important to capture? What is the best approach for this project to take to recruit service users What key inclusion and exclusion criteria would you suggest? What supports should be offered to the service user? Who should update service user data into the In-MINDD program GP, service user or researcher?

6.3.1 Information Gathering

Interviews were held with GPs and other stakeholders including; two members of an eHealth software company, two medical professionals, a sales representative of a general practice management software provider, the ICT development team, a GP and a mental health professional see Figure 11. Dr Damon Berry lecturer in Computing at the DIT School of Electrical Engineering Systems also acted in a capacity as a health informatics advisor in discussions with the researcher at a number of conferences. Topics for investigation included the ways in which service users usually source information, the types of health data routinely collected by GPs, dementia awareness, knowledge of dementia risk factors and primary healthcare software. Key stakeholders were identified with whom to interview. The purpose was to gain insight not from the perspective of the service user but rather from the perspective of the service providers in order to specify the context into which the system was designed to operate within. As two software vendors supply the majority of practices in Ireland it was important to reach some consensus about collaboration. Some examples of the types of questions asked at this stage of the research include who are the key stakeholders that we need to talk to? How do we engage with all stakeholders? How will the tool operate in practice?
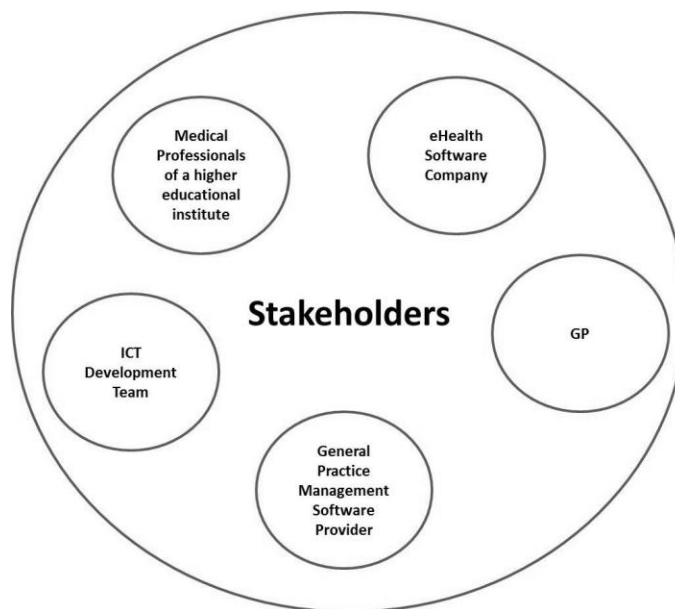
Figure 11: Phase 1Stakeholders

This research led to the production of *issue questions* (Stake, 2014) that guided the data collection and analysis process which identified requirements for the In-MINDD tool (see Figure 12). In order to build up a list of issue questions that could be used to guide data collection it was necessary to investigate the current service user landscape in Ireland. Data sources investigated during this phase of the research include diary entries, observations, meeting notes and minutes, all of which were used to create the UX specification document (see Appendix J) comprised of a set of use case scenarios, data flow diagrams and care-flow diagrams.
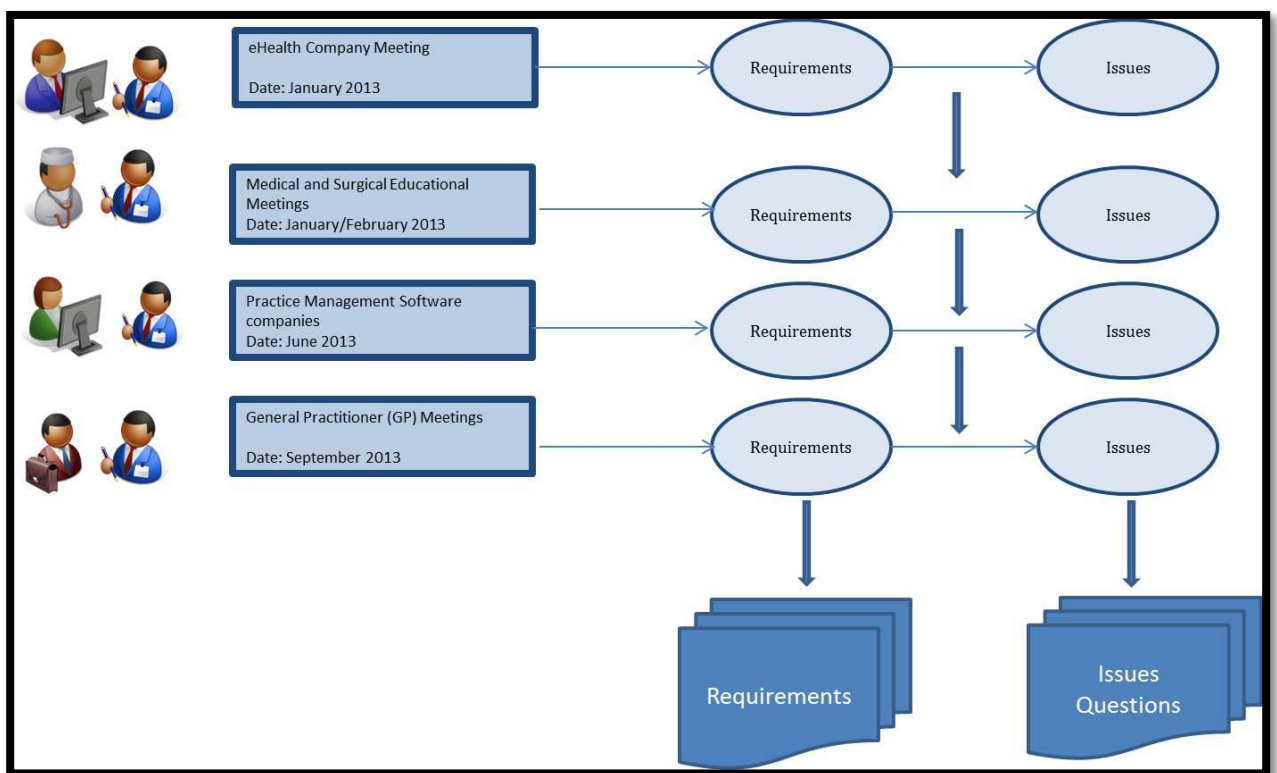
Figure 12: Phase 1 Meeting Schedule

Figure 13 indicates how the requirements specification documentation (Appendix J) was created containing both non-functional and functional requirements. Non-Functional requirements such as look and feel, usability, performance, maintainability, security and standards specify the system as a whole. Functional requirements describe what the In-MINDD tool should do and include a system description, description of system concepts, assumptions and constraints for data, data types, references documents, information on scoring, visual output examples and data processing. Data processing was further specified with the aid of unified modelling language (UML) in the user experience specification Appendix K.
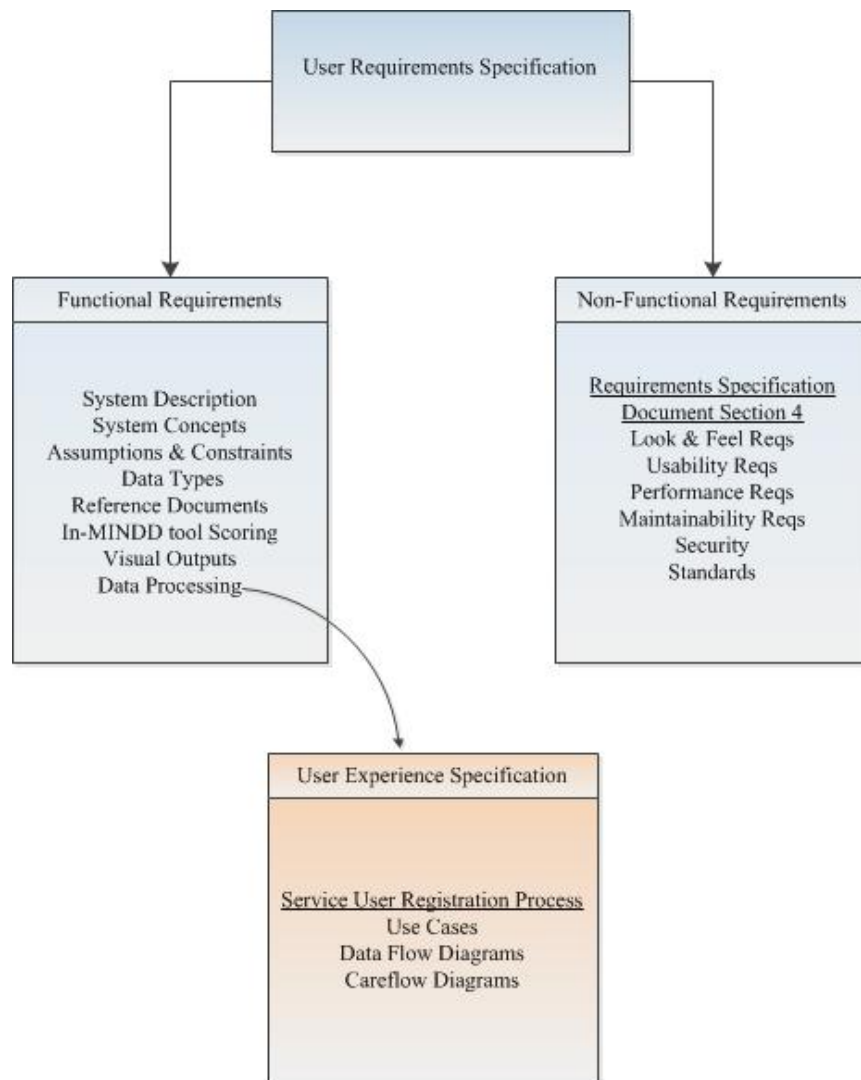
Figure 13: Requirements and User Experience Specification Documents

Stake (2014) describes a system as an assemblage of interacting things or parts into a functioning whole. While the focus of this thesis is to define requirements for a computer system it was interesting to consider the context of the system. The context was therefore also considered as a social system with independent and related functions and purposes. The first phase of this a study gathered information to define the boundaries of the system (such as time and place) under investigation, identify key stakeholders and investigate the interactions they had with the system. Moving into phase two of the research the focus would shift to GPs and service users and in Phase three service users alone.

Stake (2014) suggests that an issue should help to provide structure and help us to understand the case under study. In this instance the requirements elicitation for the development of the In-MINDD tool for deployment in the Irish eHealth context was investigated. The In-MINDD tool is the case. Issues provide a way of breaking down the case into sections for deeper analysis. In order to choose whether or not an issue was worth researching the researcher asked the following questions Stake (2014, p9) suggests:

1. Is this issue relevant to this particular case? Might inquiring about the issue help us understand the case?
2. Is there tension? Are at least two value positions present? Are there differences in opinion? Is it being argued? Even if it isn't being talked about, if it were, would there be disagreement?
3. Is it important to those in the case? Does anyone care?
4. Will it be useful to study the issue? Does it have educational implications? Does it influence how the case will be managed? Does it influence how the case will be seen?

Research conducted with the aim of becoming familiar with the Irish eHealth context into which the In-MINDD program was created for deployment can be considered phase one of this case study. Phase one consisted of qualitative research methods aimed at investigating the context or landscape into which the In-MINDD program would be implemented.

As a preliminary measure it was deemed appropriate to talk to some representatives of an eHealth software company to investigate the context within which this study was to be completed. Initial issue questions that were created as a starting point to try to help define the boundaries of the In-MINDD program and investigate the actions of users and interactions included:

Who will interact with the system? What are the requirements the system will need to function? What interactions will users have with the system? Where will users have these interactions with the system? When will users interact with the system?

6.3.2 <u>eHealth Company Perspective</u>

In January of 2013, representatives of a private sector Irish eHealth company were contacted in order to meet with the researcher to discuss the requirements gathering research. It was deemed appropriate to contact this company for its wealth of knowledge concerning the development and implementation of eHealth projects and applications aimed at the Irish market. Company members were able to quickly answer questions and provide the researcher with an insider expert view of the eHealth market in Ireland. The types of issue questions important for requirements elicitation at this stage of the research included investigating practice management software, GP attitudes to the system and how the In-MINDD system would be provided to the user. The following issue questions led the line of inquiry;

Who are the main primary care practice management software providers in Ireland?
Who are the key players in the eHealth arena in Ireland with regard to primary care?
What core requirements would GP services in Ireland want from the In-MINDD system?
What similar products are currently available on the market?
Should In-MINDD embed into the local practice management software or would they suggest it be provided separately?

6.3.2.a Data Entry

It became apparent from the interview that GPs operate in a very dynamic environment and as a consequence carry a heavy workload. Findings from the interview suggested that an Irish GP would welcome a system that does not add to the burden of existing data entry. The notion *collect once, use many times* (Barton, Kallem, Van Dyke, Mon, & Richesson, 2011) was discussed particularly in regard to repeated entry of service user data (where the GP has to re-enter service user details that have already been collected). This was identified as a real and time consuming problem for GPs and their staff. An important factor to eHealth company stakeholder interviewed was if In-MINDD would streamline data entry practice thus making the GP's job easier and differing from existing practice where much data entry is left to the GP. Stakeholders suggested that GPs were concerned about increasing workload and made it clear that In-MINDD should not produce extra data entry work for the GP stressing benefits realization. GPs would need to understand how the In-MINDD tool could be of benefit to their work.

6.3.2.b Practice Management Software

The interview provided insight into the practice management software companies stressing that software providers such as "Company A" were open to collaboration but that "Company B" would not be open to collaboration. It became apparent that certain practice management software companies were more open to collaboration with implementation research than others. At this stage of the research the In-MINDD program was envisioned as a piece of software provided through specific practice management software. As was becoming apparent not all practice management software companies were open to collaboration. It was important to identify the software companies interested in focused engagement with the In-MINDD project. By identifying the right individuals and organizations/companies it would be then possible to more easily sustain involvement, drive implementation and engage with interested stakeholders. Findings from this interview were important as they provided grounding for an important project decision. This interview led to debate among the In-MINDD project partners over whether to collaborate with practice management software

companies or provide the In-MINDD tool as a web based program. This issue would be raised again in subsequent interviews with several stakeholders.

6.3.3 <u>Irish Medical Educational Institution representatives</u>

On two occasions in January and February of 2013 the researcher and members of the research team met with representative members of a medical educational institution. During the meetings insights into the primary care context in Ireland were sought by the researcher. Ways of approaching practice management software providers were discussed with a view to investigating opportunities for collaboration. The following issue questions led the line of inquiry; *Who are the main primary care practice management software providers in Ireland?, How do we approach primary care practice management software providers with a view to collaboration?, What are the key types of data that are currently collected by GPs on service users within their practice? What are the current requirements and service user needs in regard to self-care and prevention strategies in relation to dementia?*

6.3.3.a Collaboration

During the discussion a point was raised that In-MINDD would need to collaborate with one of the practice management software companies in order to review the types of service user data collected through current practice management software systems.

6.3.3.b Demand for In-MINDD Tool

During interview the research was confronted with what Zimmerman (2000) describes as wicked questions. Zimmerman (2000) describes wicked questions as used in complex systems to explore the assumptions about an issue or situation. Stating these assumptions provides an opportunity to see patterns of thought and uncover the differences in opinions. This can lead to a common ground providing creative alternatives for stubborn problems. Wicked questions (Pawson, 2013) encourage participation in both creating the questions and searching for solutions to address them. Answers to wicked questions are rarely true or false, but better or worse (Pawson, 2013,

p.55). A wicked question posed to the researcher concerned the perceived and actual demand for the In-MINDD tool. *Is there a demand for this program?*

It was the opinion of one interviewee that there was little or no demand from the public for a program that is aimed at improving cognitive health. This implies that additional educational or cognitive health promotion initiatives on brain health function may be required by the Irish population, particularly for at risk groups before they would accept such a system.

6.3.4 <u>In-MINDD Plenary Meeting</u>

In April of 2013 the 2nd In-MINDD project plenary meeting was attended by the researcher. Plenary meetings occurred every six months for the lifetime of the In-MINDD project where representatives of each partner country met to review work carried out and plan for the subsequent months. The researcher was asked by the head of the IT development team to create a first impression of the user interface. This led to the production of the UX specification document see Section 6.4.2 Appendix J. The purpose of this request was to create a high level overview of the data inputs, processes and outputs for the In-MINDD tool profiler. To do this simple UML was used describing core functional requirements. The following action point is taken from minutes of the April 2013 plenary meeting:

- *the need to progress an outline of the user interface with the GPs and the process thereof. It was agreed that a sub-group (███████████████, KEVIN, ████████████████████████████ (TBC)), would meet to discuss this at 10.00 am Irish summer time on 7 May (may use google documents); that 'mockup' software (as outlined by ████) would be used to create a first impression of the user interface; that the initial workup of the interface would use the ten top risk factors identified by WP1's presentation;*

6.3.5 <u>GP Software Management Company Representative</u>

The number of general practice management software providers in Ireland is relatively small when compared with some of our European counterparts. According to The Irish College of General Practitioners (2014) Ireland has five General Practice Information Technology (GPIT) Group accredited GP software providers. During initial concept development In-MINDD had been envisioned as being a custom function provided by an existing practice management software program. The In-MINDD project could have sought proof of concept with one of the larger companies. Other challenges, however, such as lack of buy-in from stakeholders led to consideration by the In-MINDD project team of offering the In-MINDD tool as a web based program.

6.3.5.a   Collaboration

As mentioned by previous stakeholders it was important to investigate how open to collaboration the practice management software companies would be. Furthermore the In-MINDD team needed to know what service user details were collected by such software. The researcher had met briefly with a practice management software company sales representative at an eHealth conference in May 2013. It transpired that the software company were open to collaboration and a meeting was set up. The meeting took place in June of 2013 and took the form of a workshop to explore the best approaches with existing software provides in the GP domain. The researcher and members of the IT development team attended the workshop. The following issue questions led the line of inquiry; *Should In-MINDD be embedded into the local practice management software or be provided separately? What service user information is collected in general practice? How is information stored? How do GPs prefer to contact service users? How would one create a custom investigation for the In-MINDD lifestyle for brain health risk and protective factors? What additional functionality and features are required?*

6.3.5.b Data Entry

The sales representative reiterated that it would be challenging for the GP to use In-MINDD and their existing software systems at the same time. Such an approach would require duplication of information or repeated entry of data. It was commented that GPs would not be happy with additional data entry work. The sales representative provided a demonstration of the practice management software and responded to queries and questions from the researchers in attendance.

6.3.5.c Risk Factors

During the demonstration the sales rep highlighted patient information drop down boxes for smoking, blood pressure and cholesterol. The smoking risk factor was quite complex comprised of a drop down menu requiring different qualifiers such as options for length of time smoking, usage details. According to the interviewee this information is not always recorded by the GP. The issue of data protection was discussed with relation to cloud storage. Due to time constraints and depending on the GP there can be much variability in the amount of information that is recorded on the service user for each clinical encounter. In order to fully examine the existing user interface, the sales rep provided the In-MINDD team with a trial practice management software package for closer inspection.

6.3.5.d The Framingham Cardiovascular Risk Assessment Tool

The sales representative then gave a short demonstration of the Framingham cardiovascular risk assessment tool which estimates risk of heart attack in the next 10 years. This information was useful for the research team to review the types of functional data inputs collected (see Fig 14) on service users in Ireland using this practice management software. The three In-MINDD partner countries use similar cardiovascular risk assessment tools such as the ASSIGN or QRIKS score limited to the Scottish population and the SCORE cardiovascular risk chart used in other European countries. In the Netherlands the Framingham assessment tool is used.

Figure 14: Framingham Cardiovascular Risk Assessment Tool

Findings from this workshop suggested that in Ireland most practices use one of two dominant practice management software providers. The sales representative suggested that "*Company A*" were open to collaboration with researchers whereas "*Company B*" were not. However, not all information on the In-MINDD risk and protective factors for dementia were collected by the practice management software. This could have led to problems with accuracy for predicting a cognitive health score. Furthermore, practices that did not use the software provider chosen would have been excluded from the research. In order to create a program that would be used in as many locations as possible the In-MINDD team, following discussions, chose to prototype a stand-alone web based piece of software that would not have to depend on particular GP practice management software. The sales representative offered to create a custom investigation offered through the practice management software for In-MINDD. This investigation would have collected all the information available about a service user and produce a report through the practice management software when requested by for the GP. For these reasons coupled with the previously mentioned fear for increased data entry a

custom investigation provided by a practice management software was deemed inappropriate at the time of the study by the project team.

6.3.6 <u>GP Meeting</u>

In September of 2013 the advice of a GP was sought to help answer issue questions and provide insights on previously gathered requirements. The GP had been identified as of particular importance for having a background in general practice and ICT in Healthcare. The GP was contacted by letter (see Appendix A). In order to explain the research a short presentation introducing the In-MINDD project was given. The following issue questions led the line of inquiry: *What supports should be offered to the end user? What do GPs know about the modifiable risk factors for Dementia? The following is an example of a functional requirement question asked: who will input service user data into the IN-MINDD program GP, service user or researcher?*

6.3.6.a Data Entry

The GP initially echoed the sentiments of previous interviewees stating the In-MINDD tool should not create undue support work for the GP. The GP described how overburdened with data entry the practice already was and that the system should minimize the role of the GP in data entry. Where possible the GP suggested that data entry should be completed by the service user.

6.3.6.b Framingham Heart

The GP spoke highly of the Framingham heart study risk calculator as had been suggested for review in previous meetings. It was suggested that a system similar to Framingham utilizing a risk factor profile to predict a risk score and provide a visual output would be welcomed by other GPs. An implication for future versions of the In-MINDD tool was the inclusion of a health profiler entity with functionality to include a risk profile with detailed summary views which illustrate risk data not only for dementia but also cardiovascular disease, cancer, stroke, chronic kidney disease etc.

6.3.6.c GP Visits

The topic of GP visit was discussed briefly with the GP recommending that the project should seek to minimize GP visits resulting from the use of the In-MINDD tool. This

was in part due to the cost of GP visits in Ireland. A suggestion from the GP here was that the support environment should be comprehensive and easy to use minimising need for GP visits following use of the In-MINDD tool to discuss risk factor supports with GP. The GP responded positively to a system such as In-MINDD that in the words of the GP "*could take some of the workload off the GP*" through the use of supportive environments that recommend ways and services a service user can access and use to improve lifestyle for brain health. However, it was important to offer the service user the option of a GP visit to ensure service user safety. The decision was later made for In-MINDD to pay for the cost of one GP visit for each service user.

6.3.6.d   Service User Safety

The GP responded positively to the role of In-MINDD in raising awareness of the modifiable and preventative factors for dementia. Yet the GP was concerned for service user safety. The GP was concerned about putting extra stresses on the service user commenting that service users should not leave the practice more worried than when they had arrived. Contrastingly service user empowerment through personalised healthcare was discussed. That is according to the GP many service users want more personal involvement in their healthcare. Some service users are active participants in their healthcare being more mobile, better educated than previous generations and demanding more control over their own healthcare. The GP wanted to know more about the In-MINDD tool specifically what the interface would look like and what taking part in the randomised control trial would entail. In contrast to findings from previous meetings, the GP, was enthused about a tool that would spread awareness of modifiable risk factors for dementia and that was consistent with public health messages on cancer, heart disease, stroke etc. The GP did not query the demand for In-MINDD as had been suggested in previous meetings. Making dementia a less taboo subject was thought to be a reachable goal.

6.4: **Phase One Information Gathering Findings**

6.4.1 <u>Finding One System Design: In-MINDD Requirements Specification: A Brief Overview</u>

Information gathered was used to create the Requirements Specification document which served as the mandate for the design, development and realisation of the technical component of the In-MINDD tool within the In-MINDD Project. Sommerville (2011) describes a Requirements Specification document as intended to be non-technical and readable by those with only a cursory knowledge of the system aided by diagrams and tables (Sommerville, 2011). This document contains; a description of the In-MINDD system, an explanation of the purpose and scope of the system, a behaviour model of the In-MINDD tool, defines the system concepts, assumptions and constraints, ethical and legal requirements, functional requirements, applicable reference documents and user requirements. Here a brief overview of this document is presented available in more detail from Appendix K.

6.4.1.a   System Description and Scope

The In-MINDD tool is a web based application that was built to capture data on dementia related Risk Factors (RFs); it should contain sufficient knowledge about these concepts to allow a computer system to understand them; and finally to allow a computer system to calculate a score based on their state i.e. the measures for a specific RF. It contains logic that draws relationships between the RFs and associates each RF with one or more questions in the Question Database. In this way the system creates links from RFs to specific questions and in turn to actual data (answers) thus, building knowledge about RFs from facts. The In-MINDD tool contains two sections a profiler and support environment. The on-line profiler collects personalised demographic, lifestyle and clinical information on users. This results in individuals receiving information in the form of a personalised Lifestyle for Brain Health (LIBRA) score and profile. The support environment gives individuals information on their identified risk factors, outlines the national evidence based practice guidelines in their relevant country and supports goal setting to change behaviour.

6.4.1.b   System Concepts and Reference Documents

Service user information is collected on the following risk and protective factors: Coronary Heart Disease, Physical activity, Chronic Kidney Disease, Diabetes, Cholesterol, Smoking, Mid-life Obesity, Mid-Life Hypertension, Mood, Healthy Diet or Mediterranean Diet, High Cognitive Activity, Alcohol Consumption. Ten tabbed sections make up the In-MINDD profiler. Reference documents included four validated instruments:

- The mood section is based on a self-report depression scale called the CES-D (Radloff, 1977).
- Physical activity is based on a self-report measure of physical activity the EPIC Physical Activity Questionnaire (Wareham et al., 2003).
- Cognitive Activity – Cognitive Reserve Index CRIq (Nucci et al., 2012) - adapted (with permission) for self-administration and online use
- The Diet section is based on an adapted version of the Mediterranean Diet Adherence Screener (MEDAS) (Martınez-Gonzalez et al., 2012)

The profiler sections are named: Login, About You, About Your Mood, About Your Medical Health, Family Medical History, Physical activities, Cognitive activities1, Cognitive activities 2, Smoking & Alcohol intake & Diet. Figure 15 is a screenshot of the About You tab front end of the profiler showing the tabbed sections. Full details of the In-MINDD Profiler front- end available from the In-MINDD website: http://inmindd-profiler.appspot.com/InminddProfiler.html.

Figure 15: Screenshot of the front end of About You (Demographic) section of the In-MINDD Profiler User Interface

6.4.1.c Information Governance

In line with national policy agendas the In-MINDD programme used the Health Information and Quality Authority Guidelines for Better Healthcare Standards (2012) as a set of guiding principles to determine information governance approach for both clinical and information best practices during initial testing of prototype and to shape the guidelines for future use.

6.4.1.d Ethical and Legal Requirements

A number of ethical and legal requirements were associated with the data collected by In-MINDD. At the end of the study, anonymised data from the In-MINDD system is transferred securely to the Robertson Centre for Biostatistics (RCB) in the University of Glasgow for analysis. The Centre sits in the Glasgow Clinical Trials Unit (GCTU), a United Kingdom Clinical Research Collaboration fully registered CTU. The source data was stored on the RCB secure filestore and uploaded to the study database. Both the file store and the study database are backed up daily. Tapes were stored in a fire-proof safe every two days and stored off-site every seven days. All data handled by the RCB was anonymised and access restricted to study personnel. The RCB manages all studies in accordance with its internal standard operating procedures and all relevant legal and regulatory guidelines. It has extensive experience of managing data in the context of UK and EU privacy and data protection legislation. The RCB is certified for ISO 9001:2008 for its quality systems, has TickIT accreditation for its software development and is BS7799 compliant.

6.4.1.e Assumptions and Constraints

The In-MINDD tool is a web based program available to any users with access to the internet. The In-MINDD profiler data is collected in each country by accessing a dedicated In-MINDD password protected website. Data is collected has been held securely through the Google App Engine cloud web application

6.4.1.f   Ethical And legal Requirements

Only nominated named researchers in each country have access to the key file, which is securely stored locally by the named researcher(s). The study has been reviewed by the relevant Research Ethics Committees in each country (Ireland, Scotland, France and the Netherlands) and ethical approval has been granted. These applications require, amongst others, that the researchers give details of the security measures that have been put in place to ensure the security of collected data. As identified data controllers the researchers manage the data in accordance with national Data Protection Commissioner Requirements and EU data protection legislation.

6.4.1.g   Security Requirements

All non-functional requirements elicited from the case study are available from Appendix K Section 4. The following are examples of confidentiality, security and standards requirements:

6.4.1.h   Confidentiality Requirements

UR13 The product shall ensure that the name of participants and their data can be accessed only by authorized users.

UR14 The program shall distinguish between authorized and non-authorized users.

UR15 Each participant shall be assigned a Unique Identifier Code (UIC).

UR16 The UIC appears in the database but the password that the participant creates shall be encrypted immediately after it is entered on the registration page and remains encrypted in the database.

UR17 No personal information (e.g. name, address, date of birth etc.) shall be stored in the database.

UR18 The participant shall have the option of entering an email address.

UR19 The email address shall be encrypted immediately after it is entered on the registration page.

UR20 The email address shall be stored in a completely separate part of the database than the part that stores the responses to the questions on the screen.

UR21 The part of the database that stores the participant responses shall have no interaction with the part of the database that stores the encrypted email addresses.

6.4.1.i Standards Requirements

UR22 The encryption method for the password and email address shall create a hash for these fields using the sha1 (secure hash algorithm) outlined by DesAutels (1997).

UR23 Map patient id to the HIQA Individual Health Identifier (IHI). At the time of writing standards for the IHI were not available for the In-MINDD tool development. Standards are now available on the HIQA website:

http://www.hiqa.ie/publications/information-governance-and-management-standards-health-identifiers-operator-ireland

6.4.2 Finding Two: User Experience (UX) Specification Document

As described in Section 6.3.4 the researcher presented the requirements gathered and analysed in a User Experience (UX) Specification Document to document a first impression of the User Interface. This document would define the boundaries and the scope of the In-MINDD tool registration process. The document presented a proposed UX walkthrough told from the perspective of the service user reviewed by the ICT development team. Unified Modelling Language (UML) was used to outline the data flow through the different In-MINDD service user registration phases. UML (Sommerville, 2011) is a standard language for specifying, visualizing and documenting the models of software systems including their structure and design. As a resource UML can be used as a communication tool amongst stakeholders to clarify and define requirements. The service user's interaction with In-MINDD was understood as a process. This process involved detailing the data flow through the system with the aid of diagrams, use case scenarios and data flow diagrams. This allowed the In-MINDD team to have an overview of when, where, how, why different users would interact with the In-MINDD tool. This enabled a clear and concise overview of the intervention that each partner could query. The UX document was circulated among partner countries allowing each country to question the processes, work flow and interactions. This process allowed validation of the UX document ensuring requirements were correct, whole, meaningful, unambiguous and useful. The finished UX document was circulated in July of 2013. Phase one findings helped to shape this document and it reflects the issue questions and requirements elicited during this phase. The UX document represents a tactical output of

the first phase of the research. The document outlined the approach to recruitment, enrolment, eligibility criteria, service user registration, updating the In-MINDD profiler, the role of service user, the dementia risk reduction plan, service user approval process and the supportive environment.

6.4.2.a   Service User Registration Process

Figures 18 to 20 present extracts from the UX document. The document was developed from the perspective of the service user following analysis of the data collected as part of this case study. The UX document provides an overview of service user recruitment and registration. A great deal of the UX Document focused on the process of service user registration. A number of recruitment scenarios were created that could be queried by the In-MINDD ICT development team. Figure 18 provides a use case diagram depicting a service user registering for In-MINDD with the aid of a researcher. At the beginning of Phase 1, this process had been envisaged as the carried out with the help of a GP or practice nurse. Following findings from Phase 1of the research a key decision was made to have the participant fill in registration details with the help of a researcher.
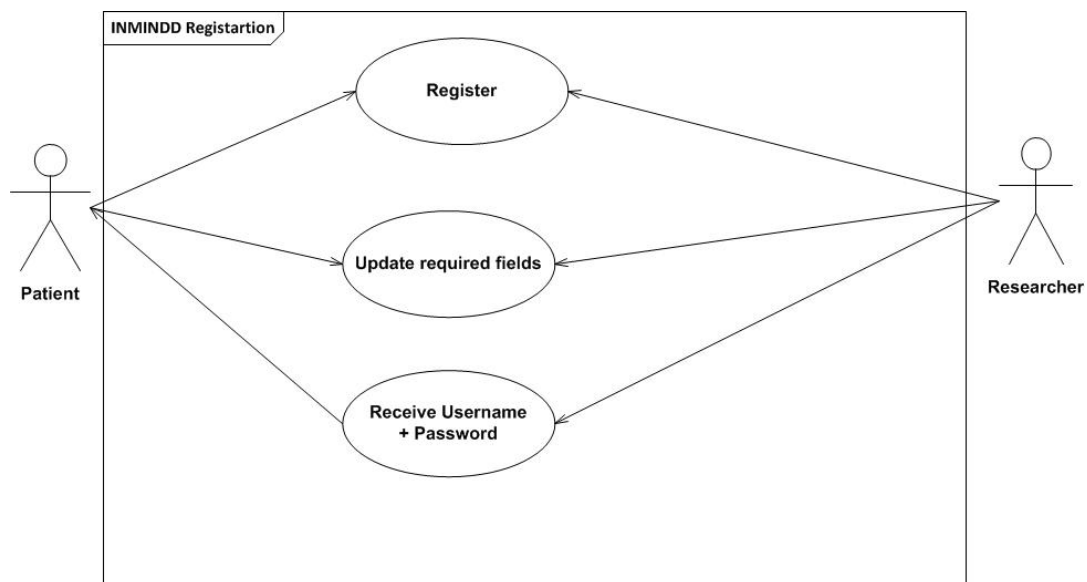
Figure 18: Service User Registration
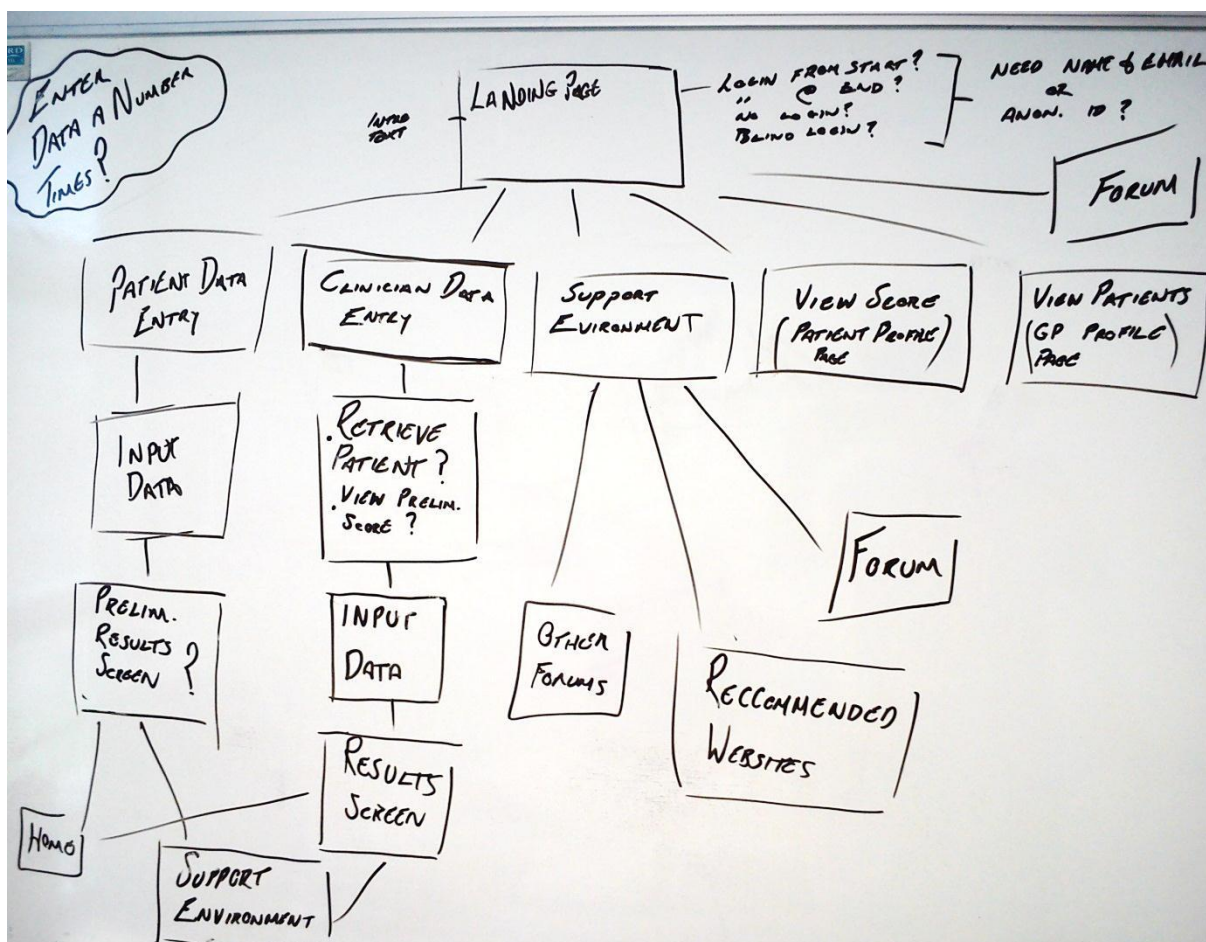
Figure 19: Example Data Flow Diagram

6.4.2.b   Single Service User Data Entry Portal

Figure 19 provides a Data Flow Diagram of the breakdown of screens for service user registration taken from a meeting with the ICT development team early in 2013. At this point in time the profiler had been designed with separate service user and clinician data entry portals. Following Phase 1 findings, the idea of a clinician data entry portal was rejected in favour of a single service user data entry portal. This was a significant decision made by the In-MINDD team following information gathering research. This led to the production of a stand-alone web based PHR tool created by the IT development team updated and owned by the service user.

This had the result of producing a more interoperable and service user centred program while reducing the workload being asked of the GP in terms of interactions with the tool for updating service user information.
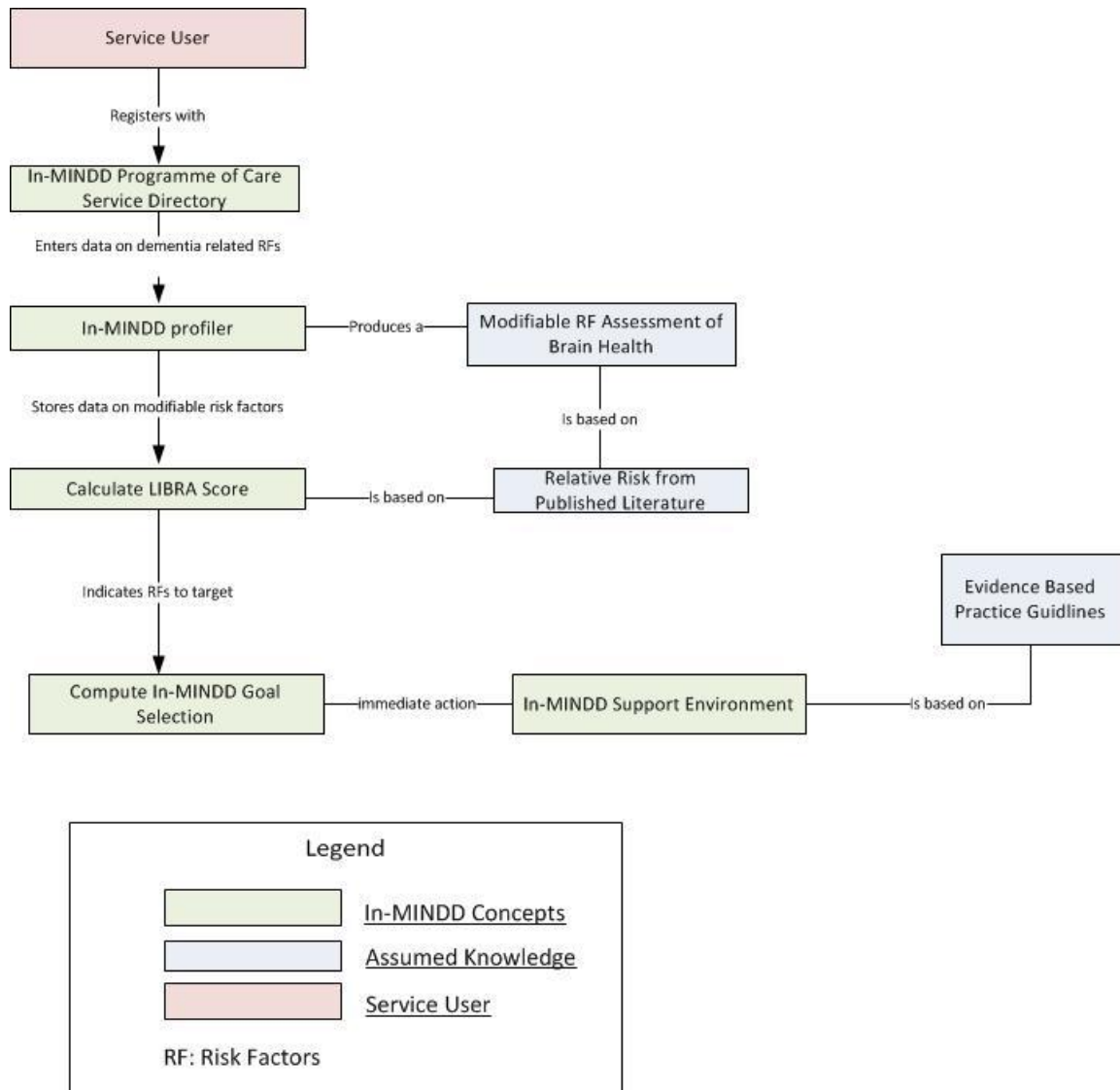
Figure 20: High level behaviour model indicating the dynamic behaviour of the In-MINDD tool.

Figure 20 is a data flow diagram outlining the flow of data through the system during service user registration. It can be seen that the clinician is no longer involved in the data entry process. The service user is now responsible for data entry.

6.4.3 Application of NPT to Findings

Findings were analysed using NPT constructs to indicate which stakeholders bought into or engaged with the information gathering research. An analysis of the findings of Phase one with regard to the first two constructs of NPT: Coherence and Cognitive participation is presented. Coherence takes into account the way a team or individual in this case identified players, operationalise a new set of practices (May et al., 2010). Table 9 indicates the players who understood the research during Phase 1.

Table 8: NPT Construct of Coherence applied to Phase 1 findings

Stakeholder	Coherence (Sense Making Work)			
	Differentiation *Is there a clear understanding of how the new e-Health service differs from existing practice?*	**Communal Specification** *Do individuals have a shared understanding of the aims, objectives and expected benefits of the eHealth service?*	**Individual Specification** *Do individuals have a clear understanding of their specific tasks and responsibilities in the implementation of an eHealth service?*	**Internalization** *Do individuals understand the value, benefits and importance of the eHealth service?*
GP	Yes	Yes	Yes	Yes
Practice Management Software Sales Rep	Yes	Yes	Yes	Yes
eHealth company members	Yes	No	Yes	Yes
Member of medical institution	Yes	No	No	No

Cognitive participation or engagement investigates the work undertaken to engage with potential users and get them to embrace the new e-health system. Table 10 indicates players who enrolled or bought into In-MINDD at this early stage of research. It can be seen from Tables 9 & 10 that GPs and Practice Management Software Sales Representatives made sense of the In-MINDD project and engaged with the In-MINDD project aims and concepts. The medical institution member interviewed did not seem to understand the need for an initiative such as In-MINDD in the context of other priorities and consequently did little to buy into or engage with the project.

Table 9: Cognitive Participation NPT construct applied to Information Gathering findings

	Cognitive Participation (Relationship Work)			
	Enrolment Do individuals "buy into" the idea of the eHealth service?	**Activation** Can individuals sustain involvement?	**Initiation** Are key individuals willing to drive implementation?	**Legitimation** Do individuals believe it is right for them to be involved?
GP	Yes	Yes	No	Yes
GP Practice Management Software Sales Rep	Yes	Yes	Yes	Yes
eHealth company members	Yes	No	na	na
Member of medical institution	No	No	No	na

6.4.3.a   Phase 1 Key Decisions

Information gathered during this phase of research led to key system and user requirements and a number of key procedural decisions. The researcher was tasked with documenting who would use the system, how participants would be recruited and how participant information would be registered with the system. Table 11 provides a breakdown of the key decisions affecting the In-MINDD project made following Phase 1 of this research. This indicates key milestone decisions which shaped the development

of user requirements. A product of these preliminary meetings was to make changes to the way in which In-MINDD would recruit GPs willing to take part in co-design. As access to primary care centres proved difficult, the decision was made to target single GP practices.

Table 10: Phase 1 Key In-MINDD decisions

Phase 1 Key Decisions		
Issue	Initial Plan	Revised Plan following phase 1 analysis of requirements
1. Delivery of the In-MINDD tool	Provide In-MINDD program through GP practice management software. Different portals for clinician researcher and service user.	To produce a piece of software that is not offered through pre-existing practice management software. Offer a stand-alone web based piece of software. Improving interoperability. Single service user data entry portal.
2. Updating Service user risk factors	GP accesses a clinician portal to update risk factors (including available BMI, blood pressure, cholesterol) from Practice	Service User receives a record sheet of critical data (including available BMI, blood pressure, cholesterol) completed by GP practice. Service User or researcher then updates this information during participant baseline meeting with In-MINDD researcher.
3. Review Risk Factors	Review availability In-MINDD risk factors in primary care?	To review practice management software risk factors collected such as Framingham Cardiovascular Risk Calculator.
4. Completion of profiler	Initially thought to be task of GP or practice nurse	To encourage service user data entry by Service User or Researcher
5. User Interface Design	Need to aid design of user interface	To create a User Experience document to be used to create first impression of the user interface
6. GP Co-design Recruitment	Target Primary Healthcare Centres	Decision made to target single GP practices
7. GP Visits	Service user urged to phone GP if support is needed following registration.	Produce comprehensive and easy to use support environment. Service User visits to GP need to be minimized.

6.5: **Summary**

This chapter presented the findings of the Information Gathering phase of the case study. Key stakeholders were identified and interviewed for their knowledge of the processes and communications that would be involved with the In-MINDD tool. The context of use of the In-MNDD tool was explored with findings presented. Information gathered was used to create the Requirements Specification (Appendix K) and the User Experience Specification Documents (Appendix J). The Requirements Specification document served as the mandate for the design, development and realisation of the technical component of the In-MINDD tool. The User Experience document was reviewed by the ICT development team to create a first impression of the user interface. This outlined the approach to: service user recruitment, eligibility, the process of service user registration, completing the In-MINDD profiler, the role of service user, the dementia risk reduction plan, the service user approval process and the supportive environment. Normalisation Process Theory was employed as a data analysis tool used to explore stakeholder engagement with the In-MINDD concept. Important case study issues at this stage included the delivery of the In-MINDD tool, reviewing practice management software and data sets, the In-MINDD user interface design, GP recruitment and creating a protocol for GP visits arising from use of the In-MINDD tool. I have clarified some of the key decisions taken at this stage such as to offer the In-MINDD tool as a stand-alone web based piece of software with a single service user data entry portal. In terms of GP recruitment single GP practices were targeted and data entry was minimized for the GP. The next phase of the case study, design in process, is covered in the next chapter.

Chapter 7: Design in Process

7.1: Introduction

Chapter 6 described Phase 1 of this case study which investigated the information gathering work undertaken to provide a clear account of the service user context for the In-MINDD tool. Findings from Phase 1 were used to document requirements and specify the user experience in order to identify the context of use of the In-MINDD tool. This chapter presents the research conducted during Phase 2 of this case study entitled: Design in Process. Phase 2 began in January 2014. The purpose of Phase 2 was three fold; (1) To recruit GPs willing to aid in the co-design of the In-MINDD Tool (2) To conduct service user focus groups to investigate the perspective of the service user (3) To build upon the requirements elicitation conducted during Phase 1 to further aid the design and prototyping of the In-MINDD tool.
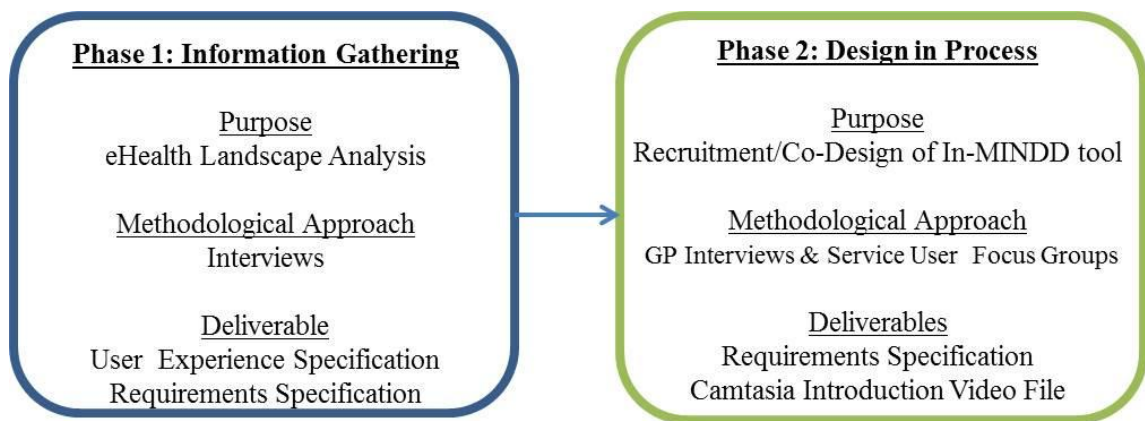
Figure 21: Phase 2 Design in Process

Issue questions and requirements elicited during information gathering were further explored in Phase 2. Whereas Phase 1 specified the initial scope of the system and the context into which the In-MINDD tool would be used, Phase 2 was concerned with the design of the In-MINDD tool interface and a more focused analysis of the support environment. Findings from interviews and focus groups were related to the ICT development team by the researcher to aid the design process of the In-MINDD tool.

7.1.1 <u>Ethical Approval</u>

Phase 2 research required ethical approval from the Dublin City University Research Ethics Committee. This process has been outlined in Chapter 5.2.1 p.71. Ethical approvals were also granted in Scotland , researchers in University of Glasgow (GU) and DCU recruited and met with general practices to get feedback on the profiler and the online support environment and its development. The In-MINDD tool could thus be developed in collaboration with primary care practitioners. Following ethical approval in July of 2013 introductory letters were sent to GPs that had been identified as having interest in the area (see appendix B). Following indications of interest from GPs, semi-structured interviews were arranged. Interview findings were fed back to the In-MINDD software development team by email and in team and plenary meetings.

This iterative process followed the components of the human-centred system development cycle discussed in Chapter 3.1.4, p.35 (Sørby, Melby, & Seland, 2005) including identifying the need for human centred design, understanding and specifying the context of use specifically the inputs processes and outputs of the In-MINDD tool. In addition this process specified non-functional or look and feel requirements (Robertson & Robertson, 2012). Human-centred design principles include the active involvement of users and a clear understanding of user and task environments. This method of design used an iterative process approach evaluating early prototypes of the In-MINDD tool taking on some of the attributes of a waterfall model (Royce, 1970) such as requirements analysis, systems design and testing with little overlap between phases.

7.2: **GP Interviews**

The aims of the interviews were to gain knowledge of the attitudes and current practice regarding dementia deterrence in general practice in Ireland, to recruit GPs willing to recruit potential service users for the In-MINDD feasibility study, receive feedback on iterations of outputs from the profiler, investigate the types of supports and services that GPs offer to improve lifestyle factors associated with dementia.

GP interviews took place during February and March of 2014. Interviews were conducted in the Dublin area with the help of two research assistants. In order to recruit interested GPs for interview letters (Appendix B) were sent to a number of GPs in the Dublin area. The letter contained an information sheet (Appendix C) explaining the purpose of the In-MINDD concept, tool and feasibility study, the purpose of the interview and what participation would involve. Participation involved one audio recorded interview, lasting no longer than one hour involving a demonstration of the online In-MINDD system and some focused discussion seeking views and opinions on the design approach, content and use.

Four interviews were conducted with one female and three male GPs willing to participate. Interviews took place in the practice of the GP usually during a quiet time of the day. The researcher read through the information sheet informing the GP about the purpose of the project, purpose of the interview, how the interview would run, how the GPs involvement would be of benefit. The GP was then asked to read and sign a consent form (Appendix D) before the discussion began. Questions chosen were based on the availability of clinical information for dementia RFs. A prepared topic schedule (E) guided interviews. Topics discussed included; (1) general knowledge of, attitudes to and current practice regarding dementia deterrence in practice, approach to service user recruitment, (2) the availability of certain clinical information variables within the model such as, BMI (Height/weight), total cholesterol and medication for high cholesterol, cardiovascular/heart disease, blood pressure levels and medication for hypertension, diabetes mellitus, chronic kidney disease, family history of dementia, family history of cardiovascular disease, levels of cognitive inactivity or physical inactivity (3) identification and recruitment of potential In-MINDD service users to take

part in planned co-design focus groups and to take part in the In-MINDD feasibility study RCT, (4) Dementia risk score examples and personalised plan and (5) supportive environment and service user supports.

7.3: **GP Interview Analysis**

7.3.1 <u>Dementia in Practice</u>

The first topic discussed during each interview was that of general knowledge of, attitudes to and current practice regarding dementia risk deterrence. GPs interviewed did not proactively address dementia in practice unless prompted by a service user. When asked if the topic of dementia risk is discussed with service users one GP interviewed suggested:

> *"Ideally you don't want to raise a hair if you can't do something about it".*

This quote indicated that some GPs would treat dementia as non–modifiable. Conversely most GPs interviewed were likely to discuss cancer or heart disease risk with their service users. A GP would target risk factors that are in common with dementia risk factors albeit to reduce the risk of heart disease, kidney failure, cancer and so forth. The following quote indicates that lifestyle factors were targeted but not in relation to dementia:

> *"No I don't think that I would talk to patients about it (dementia). I talk to patients a lot about lifestyle stuff but it is mostly cancer risk and cardiac risk that people would be conscious of. So a lot of things actually cut across."*

The following quote indicates a GP opinion that cardiovascular disease risk factors are understood by service users more so than dementia risk factors:

> *"Patient's understand their heart being protected more so than their brain being protected."*

This quote supports the notion that there is a need for a health promotion initiative and awareness campaign such as In-MINDD.

7.3.2 <u>Phrasing of Messages</u>

The way in which messages were phrased had important ramifications for user requirements for the In-MINDD tool. Some GPs insisted that dementia was discussed as something negative and that should be kept away from the attention of service users. One GP talked about phrasing the message positively. Wansink & Pope (2014) suggest that the individual is more likely to adopt the behaviour being promoted if they see that there is a potential positive outcome:

> *"You would be at risk of maybe you know Alzheimer's or something like that. But I prefer to go on the positive rather than the negative. You're preserving function, including brain function that would be the better message you know."*

7.3.2.a   User Requirements

Following a review of the relevant literature on the phrasing of health messages user requirements were created as a guide for developers and added to the Requirements Specification (Appendix K, Section 4):

> *UR2 Messages should be highlight the positive*
>
> *UR3 Give the most important information first*
>
> *UR4 Clearly state the actions users can take*
>
> *UR5 Tell the user what is to gain*
>
> *UR6 Use images to help tell the story*

Figure 22 provides outputs from the finalised support environment one can see that messages were phrased positively to highlight actions one can take to improve diet. Images are used to provide real world examples service users can follow.

Figure 22: Support Environment Outputs

7.3.3 <u>Identification and Recruitment of Potential Service Users</u>

The identification and recruitment of potential In-MINDD service users was an important discussion topic. GPs were asked to identify 6 to 8 service users who attend practice with one or more of the following dementia risk factors: Depression, Diabetes, High Cholesterol, Smoking, Alcohol, Obesity, Heart Disease, Hypertension, Cognitive or Physical inactivity. Service users would be asked to give their views on the In-MINND tool through participation in a focus group, organised by the research team. Identifying service users in terms of clinical risk factors associated with dementia did not present a problem to GPs interviewed:

> *"We use standard coding procedures for all our diagnoses in work so we have lists of people with hypertension, high blood pressure, renal disease, hypercalcaemia, cardiovascular disease etc. It would be no problem recruiting people with one or multiple illnesses."*

7.3.3.a   User Experience Recruitment Protocol

The favoured method for recruitment of service users was face to face during a consultation or via a telephone call. GPs interviewed indicated that they do not use email or text messaging to contact service users due to data protection laws. The types of communication GPs favour is telephone calls, letters or consultations. A protocol was created whereby the GP would identify eligible service users. Eligible service users would be contacted and asked to participate by the GP through face to face consultation or phone call. This would be followed by a letter from the research team when the service user had indicated interest.

7.3.4 <u>Variable Quality Data sets</u>

It became apparent that there are many gaps in the data collected and data set quality varies from practice to practice:

> *"So of the people who are attending pretty much everyone will have blood pressure, we're not as good in terms of height and BMI."*

This indicates that in Ireland quality of GP software systems data sets vary. This has long term implications for the delivery of technology to support healthcare in this country. For instance one of the GPs interviewed was unsure if they would have a height measurement for all service users. This could impact the accuracy of the dementia risk profile and score provided by the In-MINDD tool. The currency of the data held by the GPs was also a key factor, one GP made the point that service users who attend regularly would have more up to date information and prognoses than those attending less.

7.3.5 Profiler Content Questions

Overall GPs had few queries with the content of the profiler questions. The following quote gives an indication of the attitude of GPs toward these questions.

"This is all very do-able."

The question on kidney disease was queried and it was suggested that in some instances a service user may have abnormal kidney function without diagnoses of kidney/renal disease. This presented a problem for some users filling out the questionnaire. A user may present early symptoms of kidney disease and in some cases may not be aware of the fact that this is the case. A similar point was brought up about family history of dementia; in many cases people do not know if their parent(s) has or had dementia or what kind of dementia such as Alzheimer's, Vascular, Dementia with Lewy bodies etc. An important requirement therefore identified here was the need for a "don't know" radio button in addition to the yes and no radio buttons see Figure 23.

Was your mother	Dementia	Yes	No	I don't know
ever told by a doctor	Cardiovascular disease	Yes	No	I don't know
that she had :	Diabetes	Yes	No	I don't know
Was your father	Dementia	Yes	No	I don't know
ever told by a doctor	Cardiovascular disease	Yes	No	I don't know
that he had :	Diabetes	Yes	No	I don't know

Figure 23: Radio Buttons
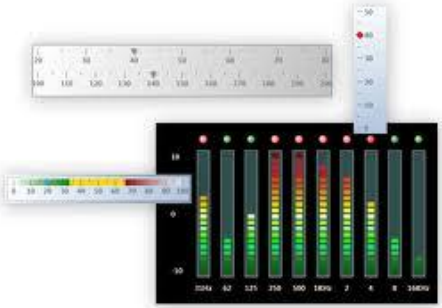
7.3.6 <u>Dementia Risk Score</u>

Two GPs interviewed preferred the name "brain health score" or "brain healthy lifestyle score" over "dementia risk score". There was an indication that this had more positive connotations. Interview findings were relayed to the project team, this led to the decision to change the dementia risk score name to Lifestyle for Brain health (LIBRA) score.

> *"That's the one I like its positive. Brain health score, brain healthy lifestyle score either of those."*

This is an example of a factual, convincing, positive gain-framed health message. Wansink & Pope, (2014) found that gain-framed messages work better than loss-based health messages. Paper prototype examples of ways of visualizing a risk score were given to GPs see Table 12. Two of the GPs liked the first example (below) for the headline risk score, followed by some histograms or bar charts for the breakdown of one's individual risk factors. A contrasting opinion was held by the female GP interviewed who thought the example images were images that would be connected to cars or racing and were found to be very male orientated. Given that dementia affects females more than males a more gender neutral image was used.

Table 11: Contrasting opinions on Example Outputs

Support Environment Output Examples	
Quote	Image
"That is the one that would really appeal to me." (male) *vs* *"I think guys would like those they are very male. That's my first impression they are all things from cars. You know I don't know how you could do it any better but that's what really strikes me. It's very male." (female)*	
"I think a headline score and maybe a histogram example 4 for different factors."	

7.3.7 <u>Supportive Environment</u>

A number of resources were suggested by GPs for inclusion in the supportive environment. Resources included local services, websites and smartphone apps. Apps suggested such as www.myfitnesspal.com can be used to aid physical exercise and count calories. Other apps suggested can be used to track jogging times such as www.runkeeper.com or www.c25k.com couch to 5k running program. The www.patient.co.uk. website was suggested which provides trustworthy medical information. GPs also referred service users to the following resources and local services: Michael Mosley 5:2 Diet program for weight loss, self-help books for depression and smoking cessation services. Some local services were suggested for inclusion in the supportive environment such as the X-pert program for diabetes and the Mater Hospital's support to quit smoking service. In Ireland, services that are available are largely dependent on the geographical area that the service user lives in. It is worth

noting that while GPs interviewed did not use email or telephone calls to contact service users, they advocate the use of technology by service users to improve health.

7.3.8 Health Literacy and Internet Access

General practices located in areas with a deprived or very deprived population reported that health literacy was low among service users.

"I think you would find a good number of our patients wouldn't use the internet"

A concern was expressed that users may not be familiar with some of the medical terminology (e.g. hypercholesterolemia, hypertension, etc.) used in the profiler, causing difficulty when completing certain questions. In addition, some concerns were expressed about the length and ease of completion of the questions contained in the Cognitive Reserve Index CRIq (Nucci et al., 2012) adapted questionnaire used in the profiler to assess cognitive activity.

7.3.9 Conclusion

The feedback from interviews was used to inform and refine the In-MINDD tool frontend. This included, for example, removing medical terminology, adding in clearer descriptions about portion sizes in relation to fruit and vegetable consumption and making presentation of cognitive activity questions more user-friendly (e.g. skip logic was used to automatically skip questions that are irrelevant for some respondents). In order to provide support during registration the decision was made to have a researcher present to clarify any service user issues. This point is significant as it had an impact on the registration process for new In-MINDD service users. GPs were on the whole positive toward the In-MINDD project. They were aware of the evidence that several health and lifestyle factors are associated with dementia risk. However, some GPs seemed to be reluctant to act on this evidence. This could be linked to poor implementation of the National Dementia Strategy (2014) in practice. GP interview findings led to changes around the process of identifying and recruiting service users, producing protocols for service user visits arising from In-MINDD, changes to content and changes to support environment information. Similar findings came from the work in Scottish In-MINDD project partners, where the views expressed mirrored those of the

Irish GPs, particularly in relation to the health literacy of the practice populations and their ability to fully understand the content. The amendments outlined above, e.g. with respect to clarification over portion sizes, addressed these issues. In the Irish context existing legislative constraints on health information access and use were evident. The enactment of the Health Information Bill and EU directive/legislation on Data Protection anticipated before end of this 2015 will address some of these issues.

7.4: **Service User Focus Groups**

As requirements gathering research shifted the focus of the In-MINDD tool it was important to conduct research with potential service users. GPs attached to the research recruited their service users. Two focus groups were held with eligible service user between May and June of 2014. Five service users (3 female, 2 male) participated in the first focus group discussion and three service users (1 female, 2 male) participated in the second focus group.

An eligibility criterion was predetermined in the UX specification (see Appendix J) by the research team and given to GPs with which to recruit eligible service users. The eligibility criteria for service users included being aged 40 to 60 years, having no mental health problems, having no cognitive impairments, able and willing to give informed consent, being established clients with the GP for 12 months and having at least one of the risk factors associated with dementia risk. Interested service users were sent a plain language information sheet by post (Appendix F) to explain the In-MINDD concept and aims, the purpose of the focus group, what participation would entail; one audio recorded focus group, lasting approximately one hour involving a demonstration of the prototype In-MINDD tool and asking for views and opinions on its design, content and use. A focus group script (Appendix H) was used to guide the discussions. Introductions were made, the aims of the research were explained and the format of the focus group was explained leading to signing consent forms. The researcher and a research assistant attended both focus groups.

As an icebreaker, participants were asked about their knowledge and/or personal experience of dementia. Following this discussion the video introduction was played. The introductory video explained the In-MINDD tool to potential service users,

stakeholders and the general public. The introductory video represents a tactical output of the second phase of the research. The introductory video described the In-MINDD concept, explained the most current information on risk and protective factors associated with dementia and demonstrated how the In-MINDD tool would work in practice. Participants were shown screenshots of the prototype In-MINDD tool and LIBRA profile examples and asked to comment. Participants were also asked about their access to computers. On completion participants were thanked and asked if they would like to be involved with usability testing of the In-MINDD tool in the following months. For the purpose of this analysis information is organized thematically combining findings from the two focus groups conducted.

The purpose of the focus group discussions was to investigate a number of issues including:

1. Understanding of existing awareness and knowledge of dementia, and impact of lifestyle on brain health to inform the requirements gathering process.
2. First impressions and opinions of the In-MINDD introductory video which provides an overview of the purpose of the system.
3. Opinions of screen shots of the In-MINDD Profiler, Brain Health Score and supportive environment.
4. Gauge participant computer literacy and assess usability of the interface design.

7.5: **Service User Focus Groups Analysis**

7.5.1 Research Queries

During this phase of the case study the most applicable research queries under consideration included:

- *Considering the NPT Constructs what* barriers and facilitators *have the potential to impact on successful deployment of the In-MINDD tool?*
- *What are the educational and training implications for stakeholders?*

7.5.2 <u>Findings</u>

An interesting finding from the focus groups was the low level of knowledge and understanding about dementia generally. In addition, participants' awareness of modifiable risk factors for dementia was low and they expressed much uncertainty about the role of various risk factors for dementia. However, participants expressed an interest in becoming informed about this and were pleased to find out that there are steps that can be taken to protect brain health and potentially reduce future risk of developing dementia. Several questions raised by participants are indicative of the level of knowledge that they had about dementia generally and about modifiable risk factors for dementia more specifically. Typical questions included:

- Is dementia becoming more common?
- If I am managing my blood pressure with medication is that the same as managing it through lifestyle changes (with regard to future dementia risk)?
- Are some of the risk factors for dementia also risk factors for other diseases or disorders (such as cardiovascular disease, diabetes, stroke, cancer etc.)?

7.5.3 <u>Dementia Knowledge</u>

Participants indicated personal knowledge of dementia from having close family members, e.g. mother, mother-in–law, aunts, having been diagnosed with dementia. Participants were unsure about the difference between Alzheimer's disease and Dementia. Another participant commented that dementia seemed to be getting more common:

"*I would know that it's getting more common*"

Informatics implications following these findings indicated the need for strong educational supports to be implemented with the In-MINDD programme. This question "Is Dementia becoming more common?" was subsequently included in the FAQ page of the support environment.

7.5.4 <u>Dementia Risk and Protective Factor Awareness</u>

Some participants indicated an awareness of the link between cognitive activity and its protective role in relation to dementia. Cognitive activity was likened to exercising the brain like a muscle. A participant talked about his mother who had had dementia doing crosswords and puzzles as a method of trying to slow the progression of dementia. Participants reported reading, playing chess, cards, scrabble as activities that could enhance brain health. This indicated an awareness of cognitive activity as a protective factor against dementia:

> "*I love scrabble and play on an Ipad against the computer. So it's all about speed and I'm aware that by doing that you're stimulating your mind but I love it anyway. Hopefully it'll keep something at bay*"

This indicated a desire for brain training resources that aid cognitive function to be included in the In-MINDD tool support environment. Participants were interested in learning more about managing dementia risk factors. A participant inquired if managing cholesterol or blood pressure with medication could help to decrease risk of disease in other areas such as heart disease:

> "*I have blood pressure and cholesterol issues so what if you are on medication for those, is that controlling it?*"

This indicated a desire for the In-MINDD tool to provide educational information around manageable risk factors such as heart disease, diabetes and chronic kidney disease. Some participants would know that they had high cholesterol but not their specific cholesterol details. There was little awareness prior to the focus group that a heart condition could impact cognitive health in later life. The following quote indicates a low awareness among participants of heart disease as a risk factor:

> "*I didn't realize that because I have a heart condition that I am more at risk*".

Participants asked about the role of genetics and queried if one has none of the risk factors associated with dementia can one still get dementia. The role of genetics is now addressed in the FAQ section of the support environment.

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7.5.5 In-MINDD Introductory Video

A Microsoft PowerPoint (2010) presentation was used to create a slideshow introduction to the In-MINDD concept and tool. Camtasia 7.0 TechSmith (2014) was then used to record this presentation using the slide show feature. Camtasia was used to enable a demonstration of an iteration of the system as part of a iterative evaluation process for early mock-up of the prototype system. The video described the most current information on risk and protective factors associated with dementia and demonstrated how the In-MINDD tool would work. The video was circulated among In-MINDD project partners to validate design and interface issues. Please see Figure 24 screenshots below.
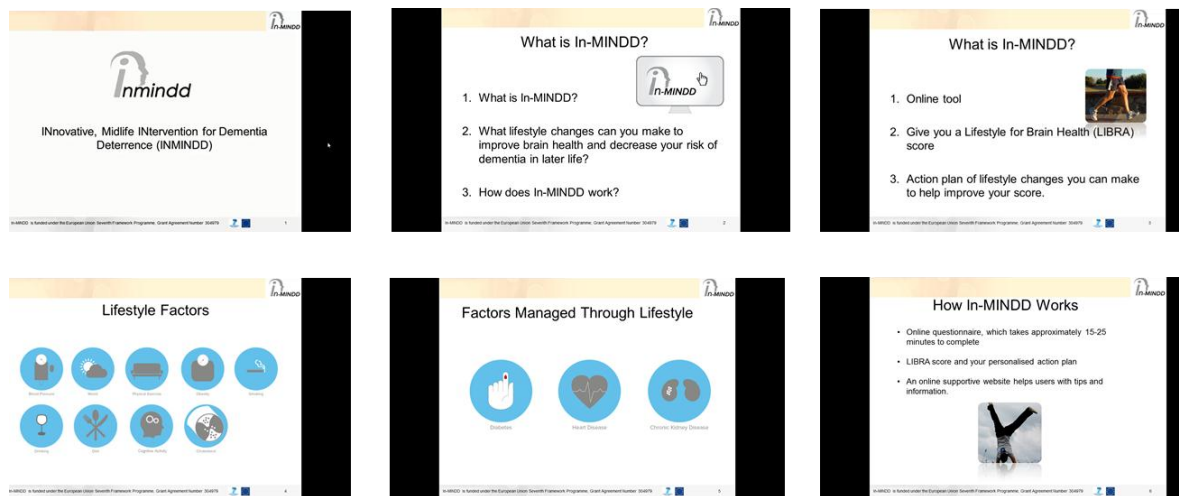
Figure 24: Screen Shots of Introductory Video

The introductory video was reported by participants to be clear and concise. However, participants did raise some issues. The three dementia risk factors that can be managed (at least partially) through lifestyle (i.e. diabetes, heart disease and chronic kidney disease) were referred to in the video as non-modifiable risk factors, and the participants highlighted the difference between these and those that are truly modifiable. The differentiation between modifiable and less dynamic risk factors is an issue that the In-MINDD research team had been considering and the video has since been changed to

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reflect this difference. Subsequently the video was added to the In-MINDD website to act as an educational aid for service users.

7.5.6 User Requirements

The following suggestions were made by focus group participants and became non-functional requirements for the Requirements Specification Document (Appendix K, Section 4). Participants responded positively to the information icons which provide explanations for various terms. Several User Requirements (UR) (see Chapter 3.1.6, p.37) relating to look and feel, usability and performance were specified such as:

- UR7 Name sections such as A1, A2, A3 to help situate users
- UR8 Provide feedback (such as a bar or a percentage meter to provide feedback)
- UR9 Shall provide a save and return function

7.5.7 Service User Registration Process

Two Participants indicated that they would like to complete the profiler at a place most convenient to the participant. Participants were found to be more comfortable using IT showing a preference for registering at home. Most participants interviewed thought they would be able to complete profiler registration at home without a researcher present.

> *"I would have thought people would have been more comfortable doing this online at home."*

Some issues were raised as to why the In-MINDD tool is provided through the web and if it could be offered offline. As with the GP interviews questions were asked about how representative a sample of the community this provides:

> *"Will you be getting a good cross section of your community?"*

Seven of the eight focus group participants interviewed expressed an interest in using the In-MINDD tool:

> *"Would love to (use In-MINDD)"*

Four participants also indicated an interest in participation in one to one usability testing of the profiler. Usability testing findings are provided in Chapter 8.

7.5.8 Support Environment

Participants were generally positive about the support environment's content. Several points were raise that usefully informed the ongoing development of the support environment. Four of the eight participants liked the facility in the support environment that allowed them to set goals and were satisfied with the goals on offer. It was suggested that the goals offered be written with a positive orientation where possible consistent with findings from Wansink & Pope (2014). Participants felt that ongoing encouragement and feedback was vital to goal attainment, and some reported that they would welcome this from their GPs as well as via the online support environment. Participants commented that they would be happy to receive email or text notifications from the In-MINDD tool. Participants suggested that encouragement and monitoring could help to keep the participant using the program month by month:

> *"I would rather be monitored over the 6 months so I actually see progress or see that I didn't make any progress and that I got to do better next month"*

7.5.9 LIBRA Score Output

Following focus group discussions it was apparent that the research team needed to create a more easily understood LIBRA score output. Findings indicated that the image used needed to be less gender specific, more clearly laid out and easier to understand. Participants did not find the horizontal bar originally developed (see Figure 25) easy to understand:

> *"That diagram, I don't think it's clear, there must be a better way of representing that information"*

Following suggestions from participants a LIBRA score doughnut (see Figure 26) was chosen as a more easily understood alternative.
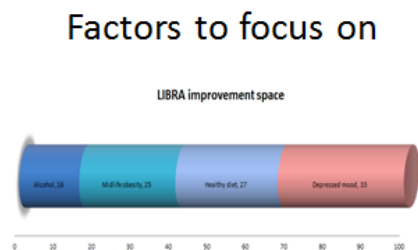
Figure 26: Horizontal LIBRA Score Chart
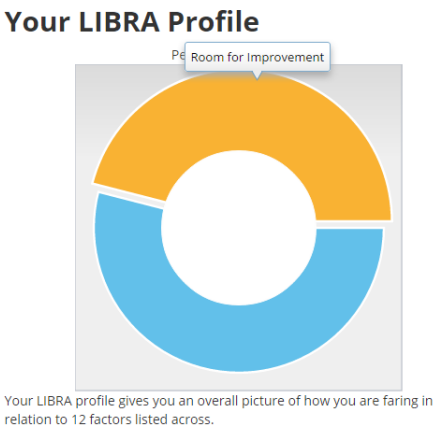
Figure 25: LIBRA Score Doughnut Image

7.5.10 Service User Supports

Participants suggested that a GP could send monthly emails or SMS text messages to participants. GPs interviewed had expressed concerns about increased workload so the decision was made to provide feedback through monthly emails sent to service users by the research team. An example of email encouraging service users to use the support environment and set goals is included in Appendix N. The "ask the experts" section of the support environment was also included as a further support. Experts are made up of Professors, Doctors, researchers and a GP from partner countries involved. Experts' responses will draw on the best available evidence about major issues and help users understand the latest research, and how it applies to their particular question. Organizational supports offered to service users included the option of having a research assistant at hand to provide aid during the registration process.

7.5.11 Conclusion

Requirements implications following findings from focus group discussions indicated among other things some anxiety around the topic of dementia. A strong educational framework needs to be included in the deployment of this programme. As a consequence of defining requirements a number of FAQ's were created for inclusion in the support environment see Table 13. Phase 2 findings helped to provide answers to the research question:

What are the current user and non-functional requirements in regard to self-care management and prevention strategies in relation to dementia risk and protective factors?

Functional and non-functional requirements elicited from this phase of the case study with respect to the In-MINDD tool are provided in Table 13. For a more detailed description of functional and non-functional (user) requirements see Chapter 3.1.5 and 3.1.6.

Table 12: Phase Two Functional & Non-Functional Requirements

Phase Two Requirements		
Section	**Functional**	**Non-Functional**
Profiler	Not Applicable	Name sections such as About You, About your Mood, Family medical history to help situate users. Provide feedback (such as a bar or a percentage meter that would provide feedback to the user about how much of the profiler was completed. Provide error message when user misses a question Provide a save and return function. Provide an online tutor or a help wizard The product shall be easy to learn by members of the public without training.
LIBRA Score	Section shall provide information regarding manageable risk factors (heart disease, diabetes and chronic kidney disease)	Messages shall be phrase positively ie (physical activity can improve brain health) Use images that are gender neutral such as LIBRA score output doughnut.
FAQ Section	Section Shall include the following questions: Is dementia becoming more common? Does Dementia run in families? What's the difference between Alzheimer's and Dementia? Will I get Dementia if I drink excessively?	Not Applicable
Useful Apps and Online Resources	Include the following resources: NHS Couch to 5k My Fitness Pal Lumosity www.citizensinformation.ie www.patient.co.uk	Not Applicable
Goals		Phrase goals positively. Messages should be gain-framed. E.g. focus on increasing cognitive health over decreasing risk of dementia.

7.6: **Application of NPT to Phase 2 Findings**

The NPT framework was used to reanalyse Phase 2 findings in order to prompt deeper analysis, the most applicable research query being:

What barriers and facilitators *impact the NPT constructs of Coherence, Cognitive Participation and Collective Action with regard to defining requirements for the In-MINDD tool?*

Here I present an analysis of the findings of the phase two with regard to the first three constructs of NPT: Coherence, Cognitive participation and collective action. For purposes of clarity, quotes from GP interviews and service user focus groups are used to provide evidence of the different components of NPT. For the GP both cognitive participation and collective action were considered to be the most applicable constructs. Overall both GPs and service users engaged with the In-MINDD concept and did achieve the construct of coherence. That is to say that service users and GPs were quickly able to make sense of the concept and agreed with the overall aims and expected benefits of In-MINDD. While service users did have some knowledge of dementia from documentaries and personal experience they were nonetheless unsure about the difference between Alzheimer's disease and dementia and had simplistic understandings of the area for example exercising the brain as a muscle. This informed the decision to include additional information on dementia as a core requirement in the support environment. Table 14 applies the NPT construct of coherence to quotes taken from phase two research findings.

Table 13: NPT construct of Coherence applied to Phase Two Findings

	Coherence (Sense Making Work)			
	Differentiation *Is there a clear understanding of how the new e-Health service differs from existing practice?*	**Communal Specification** *Do individuals have a shared understanding of the aims, objectives and expected benefits of the eHealth service?*	**Individual Specification** *Do individuals have a clear understanding of their specific tasks and responsibilities in the implementation of an eHealth service?*	**Internalization** *Do individuals understand the value, benefits and importance of the eHealth service?*
Service User	Yes *"Is there any reason why it has to be an online tool?"*	Yes *"I didn't realize that because I have a heart condition that I am more at risk".*	Yes *"Honestly I wouldn't feel I would need a researcher with me."*	Yes *"that should be emphasized that positivity that if you are managing your heart condition you are also bringing down your dementia risk"*
GP	No *"No I don't think that I would talk to patients about it (dementia)"*	No *"Ideally you don't want to raise a hair if you can't do something about it".*	Yes *"It would be no problem recruiting people with one or multiple illnesses."*	No *"Patient's understand their heart being protected more so than their brain being protected."*

It was important that stakeholder understood the potential value of this service to encourage sense making. Table 15 is useful as it illustrates GPs and service users' comments as valuable insights within the NPT framework. GPs were willing to engage and drive implementation with some reservations. Findings indicated a dearth of knowledge among both service users and some GPs of the risk and protective factors associated with dementia. Analysis of the coherence construct indicated that differentiation, specification and internalization were not achieved for GP's. this indicated a decrease in clinical engagement. Informatics implications following findings from focus groups indicated some anxiety around the topic of dementia. A strong educational framework is therefore suggested for inclusion in future deployment the In-MINDD programme in order to increase knowledge among the general public and GPs of dementia risk and associated protective factors.

Table 14: NPT construct of Cognitive Participation applied to Phase Two Findings

	Cognitive Participation (Relationship Work)			
	Enrolment *Do individuals "buy into" the idea of the eHealth service?*	**Activation** *Can individuals sustain involvement?*	**Initiation** *Are key individuals willing to drive implementation?*	**Legitimation** *Do individuals believe it is right for them to be involved?*
Service User	Yes *"Would love to (use In-MINDD)"*	Yes *"I would rather be monitored over the 6 months so I actually see progress or see"*	Yes *"Honestly I wouldn't feel I would need a researcher with me."*	Yes *"Would love to"*
GP	Yes *"That's the one I like its positive. Brain health score, brain healthy lifestyle score."* *"The patient is then taking responsibility for it. Its buy in."*	No GP's did not want to send email or SMS.	Yes *"It would be no problem recruiting people with one or multiple illnesses"*	Partial Yes *"Ideally you don't want to raise a hair if you can't do something about it".*

Both stakeholders achieved cognitive participation as can be seen from quotes in Table 16. Service users and GPs bought into the idea of the core idea of the In-MINDD concept for a sustained time period and became drivers of implementation suggesting ways in which the program could be changed to better suit the service user. GPs had some reservations such as concerns about increased data entry work and some paternalistic responses. The following quote indicates engagement with the In-MINDD concept achieving "buy in" with service users:

> *"Would love to (use In-MINDD)".*

Table 15: NPT construct of Collective Action applied to Findings of Phase Two

	Collective action (Enacting work)			
	Skill set workability *How does the innovation affect roles and responsibilities or training needs?*	**Contextual integration** *Is there organizational support?*	**Interactional workability** *Does the eHealth service make peoples work easier?*	**Relational integration** *Do individuals have confidence in the new system?*
Service User	*"Honestly I wouldn't feel I would need a researcher with me."*	Yes Support provided by the research team and support environment	nb Service users don't use In-MINDD in work	Yes *"Would love to (use In-MINDD)".*
GP	Yes Need for Dementia risk factor awareness campaign *"it is mostly cancer risk and cardiac risk that people would be conscious of"*	Yes Some support provided by GP	No	Yes

7.6.1 <u>Collective Action</u>

Following analysis of material using the NPT construct of Collective action the registration process was identified as needing organizational support for the service user. Service users asked for feedback and encouragement with frequent monthly emails or sms text messages. Interestingly service users did not indicate a need for a researcher to help them register with the program. However in order to reduce errors during the feasibility study and ensure registration is completed in full the decision was made to have service users register with the aid of a researcher.

This is reflected in the usability requirement (see Appendix K, Section 4):

Usability Requirements

UR10 The website shall be easy to use by a member of the public without training with the aid of a researcher if needed.

Participants commented that they would be happy to receive email or text notifications from In-MINDD. Participants requested encouragement and monitoring. GPs were worried about increased workload. The two issues brought up with GPs were data entry and an increase in service user visits due to participation with the research. Increased workload was identified as the most important risk to GPs. Steps taken to negate risks included providing a researcher to aid service user registration.

7.6.2 <u>Phase 2 Key Decisions</u>

Table 17 provides a breakdown of the key decisions affecting the In-MINDD project made following phase two of this research. This table shows how issues developed through the first two phases of the case study.

Table 16: Phase 2 Key Decisions

Phase 2 Key Decisions			
Issue	Initial Plan	Revised Plan following phase 1	Plan Following Phase 2
1. Updating Service user risk factors	GP accesses a clinician portal to update risk factors (including available BMI, blood pressure, cholesterol) from Practice	Service User receives a record sheet of critical data (including available BMI, blood pressure, cholesterol) completed by GP practice. Service User or researcher then updates this information during participant baseline meeting with In-MINDD researcher.	Service user registers with clinical information received in letter from GP. Researcher is present to provide assistance.
2. Review Risk Factors	Review availability In-MINDD risk factors in primary care?	To review practice management software risk factors collected such as Framingham Cardiovascular Risk Calculator.	Risk factor information differs from practice to practice in Ireland. Indicating that poor quality data sets in primary care. This impacts LIBRA score accuracy and has implications for future PHR and IHI.
3. Completion of In-MINDD Profiler	Initially thought to be task of GP or practice nurse	To encourage service user data entry by Service User or Researcher	Data Entry is task for the service user.
4. User Interface Design	Need to aid design of user interface	To create a User Experience specification document to be used to create first impression of the user interface	Incorporate non-functional requirements in the In-MINDD profiler
5. GP Co-design Recruitment	Target Primary Healthcare Centres	Decision made to target single GP practices.	GP practcses recruited for co-design research
6. GP Visits	Service user urged to phone GP if support is needed following registration.	Produce comprehensive and easy to use support environment. Service User visits to GP need to be minimized.	GP Visits minimized through comprehensive support environment.

7.6.3 <u>Context, Mechanism, Outcome Configurations</u>

In Chapter 4.2.3, (p. 53) critical realism was discussed as a practical tool to with which evaluate health and social care programme implementations from the perspective of outcomes delivery. In phase two the Context, Mechanism and Output (CMOc) configurations suggested by Pawson & Tilly (1997) are used to investigate a theory that a programme works (o) due to the action of some underlying mechanism (m) which only comes into action in particular contexts. CMOc's are stated as if-then equation: if the

right processes function in the right circumstances then the programme may succeed. It is important not to overstate the accuracy of CMOc as there is variability from service user to service user. Phase 2 uses CMO configurations to consider how the programme as a mechanism can be used with service users to illustrate the context and potential outcome.

Table 17: Phase 2 CMO Configurations

Phase 2 CMO Configurations		
Context	**Mechanisms**	**Outcomes**
Individual and their perception of their health state as indicated by the personal health record assessment.	In-MINDD support environment	Potential for enhanced health outcomes
Individual's motivation and capacity for engagement with the personal health record.	In-MINDD support environment	Potential for enhanced health outcomes
Individual's health state as indicated by the personal health record assessment.	In-MINDD support environment	Potential for decreased health outcomes
Individual's residential environment.	Appropriate access to hardware and broadband internet.	Potential for enhanced health outcomes

as can be seen from Table 18 the outcomes which can be provided through the use of the In-MINDD tool support environment is potential for enhanced health outcomes as a consequence of modifiable lifestyle behaviours. Potential for enhanced health outcomes here involve increased dementia risk factor awareness and increased health literacy leading to enhanced health outcomes. Mechanisms that have been identified as enabling

these outcomes include use of the In-MINDD support environment, receiving personalised supportive emails, setting of personal goals that identify risk factors and visiting the GP. Increased health literacy and insight into health state can be achieved through regular engagement with reliable information provided by the mechanism of the support environment. Personalised goal setting and reliable supportive and alert emails are the mechanisms which can be provided by the In-MINDD tool which can further enable increased health literacy and better potential for health outcomes in the future. It is important to note here that there is a potential for anxiety or stress in some individuals using the In-MINDD tool which could lead to decreased potential health outcomes. This has implications for the service user suffering from anxiety or a variety of health problems. GP visits are another mechanism provided to help increase dementia risk factors awareness among service users. GPs interviewed in Ireland expressed a wish to limit the number of GP visits. This is directly related to the cost of GP visits in Ireland. This mechanism may work more successfully in partner countries such as the Netherlands where GP visits are free. The In-MINDD introductory video proved a successful mechanism in the context of service user registration to increase awareness of dementia risk factors and increase knowledge of the In-MINDD tool.

7.7: **Summary**

This Chapter presented the findings for the Design in Process phase of the case study. Findings were presented from GP interviews and service user focus groups. Findings led to changes around the process of identifying and recruiting service users. Protocols for service user visits arising from In-MINDD were refined following this phase. Non-functional requirements were further specified in the Requirements Specification Document most notably in terms of the phrasing of health messages (positive, action based, highlight positive actions), output images (provide gender neutral images) and other look and feel requirements. The ICT development team made changes to the In-MINDD support environment content in light of this. Functional requirements were specified for the content of the support environment such as Questions for the FAQ page and a less gender specific LIBRA Score Output.

An analysis of findings using the NPT framework identified the service user registration process as needing organizational support. Some paternalism was identified on the part of GPs in terms of reluctance to share information about dementia risk with service users. This indicates that a strong educational framework is needed to accompany future deployment the In-MINDD programme in order to increase knowledge among the general public and GPs of dementia risk and associated protective factors. Service user representatives appealed for a support environment that would provide personalised feedback, encouragement and monitoring. Consistent with findings from stakeholders interviewed in Phase 1, GPs were found to have concerns for increased workloads. Steps taken to negate these concerns included reducing the role of the GP in the registration process and using In-MINDD researchers to aid with service user registration. Primary Care data sets were found to be of variable quality providing further reasoning behind offering the In-MINDD tool as a web based PHR.

Chapter 8 describes the evaluation stage of the requirements development research. This chapter explores usability testing research carried out with participants to iteratively evaluate prototypes based on the requirements gathered in the earlier phases.

Chapter 8: Evaluation

8.1: Introduction

Chapter 7 described the research and findings elicited during the second phase of the case study. This chapter describes the third phase of this case study entitled Phase 3: Evaluation see Figure 27. It is important to mention two key points: that this was a iterative evaluation to test initial identified requirements as the In-MINDD tool was not yet fully operational and as such this chapter is an evaluation of the contribution of this researcher to the co-design of the In-MINDD tool. The purpose here was to iteratively evaluate the prototype In-MINDD tool by usability testing in order to relate findings to the ICT development team in order to improve design and to check if it satisfied specified user and organisational requirements (Sørby, Melby, & Seland, 2005) elicited during initial development phases. The In-MINDD RCT commenced following the completion of the In-MINDD PHR. Qualitative interviews conducted with the In-MINDD RCT participants were analysed and presented here to validate the requirements gathered. This is consistent with section 6.3-6.4 of the HCD principles (ISO, 2010) available in Chapter 3.1.4, p.37.
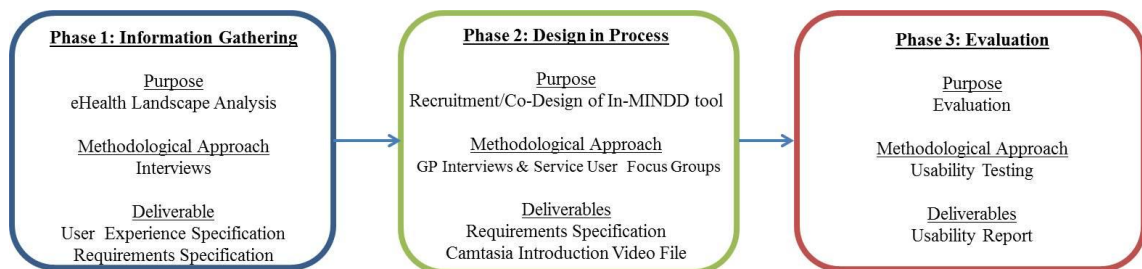
Figure 27: Phase 3 Evaluation

The core research method employed during this final phase of the case study was that of usability testing. Sections of the usability report are related here to evaluate the design of the In-MINDD tool. Screen shots of the In-MINDD profiler and support environment are provided in the following pages and problems encountered by participants using the system are related.

8.2: **Method**

Phase two research was concerned with eliciting requirements and gaining deeper understanding of service user requirements with regard system design and user experience. Phase 3 of the case study research consisted of usability testing of a In-MINDD website prototype. The prototype of the In-MINDD profiler and paper prototypes of the In-MINDD Support Environment. Gould and Lewis (1985) suggest that in order to investigate how well a website works a usability test is required. A usability test involves providing a potential service user with scenarios to complete while recording their performance, thoughts and attitude (Gould & Lewis, 1985). Testing of the In-MINDD tool was iterative with findings from tests reported to the IT development team, for redevelopment followed by repetition of the process.

8.3: **Usability Testing**

Usability testing was carried out to check for bugs, try to break the system, seek new perspectives on the system and evaluate the usability of the In-MINDD tool. Test results were related to the IT development team in order to improve front end design and to check that stakeholder requirements were met. In addition to the In-MINDD team testing the tool, four participants aged 40 to 60 years took part in usability testing (2 female, 2 male) between July and September of 2014. Participants were recruited from the same population that had taken part in focus groups during phase two research. Tests were carried out at a time and location convenient to the participant and researcher. The researcher read through a prepared test script (Appendix I) informing participant about the purpose of the usability test, purpose of the research, how the test would run and how involvement would be of benefit. Participants accessed the web based programs

using a laptop made available by the researcher. Each session took approximately forty minutes. Participants were given a username and password and asked to register as a new user. Participants were asked to follow the prompts and ask researcher if help was needed. Participants were audio recorded.

Participants were given two scenarios to complete. Firstly participants were asked to register as a new service user and update information for all sections of the profiler. Secondly participants were asked to view their LIBRA score and give feedback on the look and feel to the researcher. Participants were encouraged to try to think aloud during the usability test and let the researcher know of any thoughts or opinions that occurred. The researcher observed, taking notes when a participant had a query or problem using the profiler. When participants had completed the two scenarios they were thanked for participating in the research.

8.4: **RCT Qualitative Interviews**

As part of the RCT the programme team conducted qualitative interviews with participants, GPs and practice nurses to explore their use of the LIBRA score and profile. Participants were interviewed as they neared trial completion, to understand how they had used the intervention, what lifestyle changes they had made and whether, or not, they had been successful. A smaller sample of practitioners was also interviewed in Ireland and in Scotland (Table 18).

Table 18. Interviewees in each country

Country	Participants		Health Professionals		Total
	Baseline	6 months	Baseline	6 months	
France	5	5	-	-	10
Ireland	7	11	3	2	23
Netherlands	5	5	-	-	10
Scotland	10	8	5	5	28

8.4.1 Respondents

A total of 56 participants were interviewed across the intervention and control arms. Ten interviews were conducted in France and in the Netherlands, 11 in Ireland and 18 in Scotland. More intervention participants (n = 35) were interviewed than controls (n = 14); 22 were male and 27 female.

8.5: **Usability Testing Findings**

8.5.1 Usability Testing Analysis

Tape based analysis (Krueger, 1998) was used during usability testing to capture notes. The audio recordings of the usability test were transcribed and abridged transcripts (Appendix Q) containing relevant and useful portions of the usability tests were created. A primary analysis was conducted immediately after each usability test to make sense of written notes while they were still fresh in the mind. Further analysis involved reviewing the raw data, interpreting the results, categorising results in terms of website sections. All participants completed the registration process in less than one hour and were able to complete both scenarios given. The following In-MINDD profiler sections were found to warrant the most queries; About You, Mood, Family Medical History, Physical Activities, Cognitive Activities, Smoking & Alcohol.

8.5.2 The About You Section

The text field for age allowed three digits see figure 28. In-MINDD service users are aged between 40 and 60 years. This field should allow 2 digits instead of 3. An error message occurred when the participant entered an age and not a year of birth. The participant found this error message useful to bring ones attention to the error and fix it.

Figure 28: About You section of In-MINDD Profiler

8.5.3 Requirements

A number of functional and non-functional requirements were identified following usability testing. Table 19 presents functional and non-functional changes proposed to the In-MINDD profiler sections. Findings were fed back to the IT development team, changes were made to the profiler and the resulting iteration was tested. The following requirements were related back to the IT development team in order to improve the In-MINDD profiler:

Table 19: Phase Three Requirements

Phase Three Evaluation		
Profiler Section	**Functional**	**Non-Functional**
About You	Message needed to prompt user to go to the about you section when registration details have been submitted.	Answers should be aligned right Text field for age should only allow two digits
Smoking & Alcohol	No requirements	Text field should not allow future years only years past from the present date.
Family & Medical Health	No requirements	Second question change the word mother to father
Mood	No requirements	Section needs a vertical scroll bar

8.5.4 LIBRA Score Analysis

Findings from Phase 2 section 7.3.2a provided user requirements specifying the wording that educational messages on dementia related risk and modifiable factors required positive action based, gain framed messages (See Appendix K, Section 4).

UR2 Messages should be highlight the positive

UR3 Give the most important information first
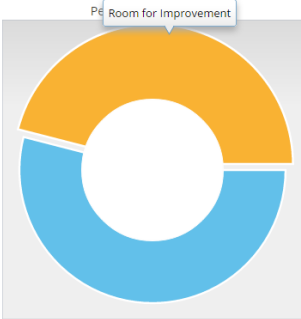
UR4 Clearly state the actions users can take

UR5 Tell the user what is to gain

UR6 Use images to help tell the story

The LIBRA profile was separated into three sections; Keep it Up, Room for Improvement and Remember to manage well. Information was chunked in three different sections in order to facilitate understanding of the risk, protective and non-modifiable factors that have a role in one's overall LIBRA score. Simple positive idioms were used to convey meaning. The "Keep it Up" section refers to dementia risk or protective factors that service users are currently managing well and conditions which they currently do not have. The "Room for Improvement" section includes areas which could be targeted for behaviour change strategies, for example smoking or physical inactivity. The "Remember to Manage Well" section concerns manageable conditions such as diabetes or coronary heart disease. The same user requirements guided the formulation of such as the LIBRA score outputs. Table 20 provides feedback given on paper prototypes of the LIBRA Score.

Table 20: LIBRA Score Findings

LIBRA Score	
The Room for improvement section was found to be confusing. The participant thought that cognitive activity, mood, diet, blood pressure, obesity, smoking, cholesterol, physical activity and alcohol consumption were part of the room for improvement score. This was not the case. The participants only had blood pressure and diet in his actual room for improvement score.	
LIBRA Doughnut

There was some confusion around the LIBRA score doughnut. This needed some explaining to participants. | |

Content within the first image cell:

The LIBRA profile is divided into three parts:

Keep This Up

Your Keep This Up Score is **82%**
This score is based on a sum of all those factors where you are doing well. These factors are presented below.

- Cholesterol
- Cognitive Activity
- Diabetes

Room for Improvement

Your Room for Improvement Score* is **18%**
If you are not faring so well in any of nine factors listed below, these are included in your Room for Improvement score:

- Cognitive Activity
- Mood
- Diet
- Blood pressure
- Obesity
- Smoking
- Cholesterol
- Physical Activity
- Alcohol consumption

*Your Room for improvement score is a sum of the factors where there is scope for improvement. The following factors are included in your Room for Improvement score:

- Blood Pressure

Remember to Manage Well

Your Remember to Manage Score is **0%**
If you reported that you have none of these conditions, no icons will appear below.

A Remember to Manage Score applies where you have reported that you have diabetes, renal dysfunction or heart disease. Your Remember to Manage Well Score is made up of the sum of these factors reported by you when completing the profiler.

Your responses tell us that you need to remember to manage the following well with the support of your GP

- Cholesterol

What do I do next?

Managing these conditions will not change your LIBRA profile or your Keep It Up score, but it is important that you manage these conditions effectively to maintain good health. Adopting a healthy lifestyle will help you to manage these conditions. Click on any of the icons above to learn why it is important to manage these conditions

Content within the second image cell:

Your LIBRA Profile/Score

Thank you for completing the In-MINDD profiler. Below you will find your LIBRA profile and score.

Your LIBRA Profile

Room for Improvement

Your LIBRA profile gives you an overall picture of how you are faring in relation to 12 factors listed across.

What is the LIBRA profile and score?

LIBRA stands for Lifestyle for Brain Health. The LIBRA profile and score are personal to you. They are based on the responses that you have given to the questions in the In-MINDD Profiler pertaining to 12 different factors related to lifestyle. There is evidence to show that these 12 factors can impact on your brain health and can influence your chances of developing dementia in later life. These factors are:

- Cognitive Activity
- Mood
- Diet
- Blood pressure
- Obesity
- Smoking
- Cholesterol
- Diabetes
- Chronic Kidney Disease
- Heart Disease
- Physical Activity
- Alcohol consumption

What does my LIBRA profile and score tell me?

Your LIBRA profile and score have been calculated to give you an overview of your Lifestyle for Brain Health.
We have devised your personalised plan based on the information you provided when completing the In-MINDD profiler.

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8.5.5 Mood Section

Figure 29 provides a screenshot of the mood section. Service users found navigation difficult. It was difficult to access the submit button as the user needed to scroll vertically down the page. One participant felt that questions were negatively phrased however the mood questions are based on the CES-D (Radloff, 1977) self-report depression scale and cannot be altered. Some participants found some questions difficult to understand. When filling out the mood section the alternate shading of questions was found helpful as a visual cue for ease of reading.

Figure 29: Mood section of the In-MINDD Profiler

8.6: **RCT Qualitative Interview Findings**

Findings of qualitative interviews conducted by In-MINDD programme team members as part of the In-MINDD RCT were reanalysed by the researcher and relevant quotes are presented in the following sections. Data was analysed to validate the requirements gathering research in terms of clinical engagement. Both RCT participants and practitioners were interviewed about their experience and views of the In-MINDD profiler, the LIBRA profile and the support environment. NPT was used to guide the qualitative process evaluation.

8.6.1 Support Environment

Participants liked the information they received from the profiler, and the reinforcement from goal setting. For some, however, the on-line support environment was thought to lack interactivity. The following quote specifically mentions a lack of engagement and interactivity in the support environment.

> *'I visited the website, I looked at the profile but, the profile was interesting but there **wasn't anything else that was encouraging or engaging**, you know, like a call to action really. It was all just information ..... In terms of what would be useful I think the potential for the website [the In-MINDD support environment] to be supportive it could be ... but it **needs to be some way that you could interact with,** like **the goals are very, like you read them and you forget them** (laughs)' (ID1103001, Ireland, Male, Intervention arm, 6 month interview)'*

Some found the website easy to navigate, while others found it more difficult. This may be linked back to individual's computer literacy; however, this was not fully explored with interviewees.

8.6.2 LIBRA Score

Control group participants were asked about risk factors that had been identified in their "room for improvement score" and what they had done as a result. Many participants had received "room for improvement" scores in relation to smoking, diet, and/or physical activity. Areas targeted included diet and cholesterol, and changes to diet were particularly popular:

> *'... I'm thinking more in like vegetables, fruit and white meats as opposed to red meats because I have a bit of bother now when I eat red meat. .... Hopefully I'm cutting down on my drinking, but that varies' (ID2204009, Scotland, Male, Intervention arm, 6 month interview)*

> *'Well I have porridge for breakfast about four times a week now. For breakfast, the toast is gone. **And we have made a conscious effort, the pair of us, to try and reach our five a day fruit and veg. …. We've definitely improved our food intake.**' (ID1107033, Ireland, Female, Intervention arm, 6 month interview)*

8.6.3 Goal Setting

The goal setting option was found helpful and a number of interviewees talked about using it, particularly in relation to exercise and diet targets. However, others had not engaged with this feature and it was not clear that they would

'Interviewer: ... did you get as far as setting any particular goals on the website?

*Interviewee: **On the website no, but I'm going to do that'** (ID2201019, Scotland, Female, Intervention, Baseline interview)*

8.6.4 Engagement

Achieving engagement was acknowledged as requiring many approaches, of which In-MIND was just one aspect. Some of the interviewees in Ireland also spoke about the limitations of an online intervention and the importance of face-to-face interaction and peer-to-peer support and other approaches, opportunities to engage in debate about lifestyle changes for brain health and other approaches to support them in making lifestyle changes.

*'**… it's just about a broad approach [to making change] where you get it from several different angles and it's just engagement**. …. I ended up at the end of the year, I suppose, much better informed than I would be at the beginning of the year and it wasn't particularly this [In-MINDD] but a culmination of things.' (ID1103001, Ireland, Male, Intervention arm, 6 month interview)*

The numerical value received in the LIBRA profile was generally well received and most seemed to understand the score and what contributed to that. Some were surprised, and even disappointed, by their "room for improvement" score as they thought their lifestyle was generally healthy.

'Interviewer: And 57% felt like a rubbish score to you …

Interviewee: Yes I was quite shocked at that' (ID 2206031, Scotland, Female, Intervention arm, Baseline interview)

8.6.5 GP View of In-MINDD PHR

Qualitative data was gathered during focus groups with HCPs in participating practices; these were held in Ireland and Scotland. The participants included general practitioners, practice nurses and practice managers. Findings were analysed and are presented here under two categories context of use and social technical fit.

8.6.6 Context of use

Views were mixed over whether primary care is the best context for an intervention such as In-MINDD. It was discussed that there was a need for more non-medicalisation of health and that there may not be the capacity in general practice for taking on the extra work that might be associated with In-MINDD. There was feeling of an increasing need for people to take personal responsibility for their own health. The influence of communities and public campaigns was also mentioned in triggering patients to make change. This finding is consistent with findings from the requirements gathering research. It suggests that the best way to ensure clinical engagement is to offer the end user the In-MINDD tool as a web based PHR.

8.6.7 Social and Technical Fit

Some suggested that the information was rather vague and that there might be need for more specific or individually tailored information provided in the support environment. IT access and literacy and difficulties associated with online only resources were seen as a barrier to people engaging with the intervention. It was felt that the use of apps or smartphones might make the intervention more accessible, and that there would be a need for different approaches to make it suitable for all potential users. This finding is in keeping with findings from focus groups conducted as part of the case study related in Chapter 7 suggesting that interactivity and access need to be increased to achieve engagement with all potential end users.

8.7: **Conclusion**

This chapter presented the findings of the evaluation phase of the requirements development for the In-MINDD tool. Findings have been presented from usability testing carried out with service users to iteratively evaluate initial prototypes of the In-MINDD tool. Findings were used by the ICT development team in order to troubleshoot design problems, fix usability issues and bug fix. Usability testing was found useful to refine prototypes reducing errors in the user interface design. A number of non-functional errors were found related to user interface design issues such as text

alignment, length of text fields and the need for vertical scroll bars. Paper prototype iterations of the LIBRA score outputs were reviewed and reiterated. Findings of RCT interviews were presented to validate engagement with the In-MINDD tool.

8.8: **Case Study Summary**

This section provides a summary of the Case Study of the requirements development process for the In-MINDD tool. Phase 1 of the case study presented an exploration of the context of use for the In-MIND tool. The researcher met with a number of identified stakeholders such as GP's, medical educational institution members, eHealth software company members, practice management software company sales representative and the In-MINDD IT development team. Stakeholders were of interest for their knowledge of the processes and communications that would be involved with the In-MINDD tool. Findings indicated that the best way to offer the tool was a stand-alone web based PHR piece of software not linked to primary care systems having a single service user data entry portal. Important case study issues included the delivery of the In-MINDD tool, practice management software systems and data sets, user interface design, GP recruitment and protocols for GP visits arising from use of the In-MINDD tool.

Phase two of the case study presented the design in process phase of the requirements development research. The purpose of this phase was to specify user and organisational requirements. Data was collected through interviews with identified GPs and service user focus groups. GPs were found to be reluctant to increase their workload in terms of data entry and increased service user visits. Service user representatives appealed for a support environment that would provide personalised feedback, encouragement and monitoring. Primary care data sets were found to be of variable quality providing further reasoning behind offering the In-MINDD tool as a web based PHR updated by the service user.

Phase three presented the iterative evaluation research conducted with identified service users of the user interface design of the In-MINDD tool. Iterative evaluation through usability testing served to troubleshoot design problems, fix usability issues and bug fix (see Table 20 p.147).The system had satisfied user and organisational requirements, was

fit for purpose and was deployed in the feasibility study following this research. The system goal created in phase 2 of the case study was met as all participants completed registration in under an hour with the help of a researcher. Had the researcher more time in the field another round of usability testing could have tested the functioning support environment, however, this was real world research bound by time constraints. This concludes the case study report. The next Chapter will explore and analyse the findings of the case study drawing conclusions and implications of the research in relation to literature, policy and the future for the In-MINDD tool.

Chapter 9: Discussion

9.1: Introduction

This case study presented an investigation into engagement processes for user requirements development for a PHR aimed at health self-management. Specifically the case study investigated the user requirements elicitation process for the co-design of the In-MINDD tool, a PHR aimed at self-management of dementia risk and protective factors. The purpose was to investigate: the context the In-MINDD tool was designed to function and operate within; describe key stake holder needs; develop user requirements; gain feedback on successive prototypes of the In-MINDD tool and to iteratively evaluate the tool. The approach adopted was intended to optimise the effective development, implementation and integration of the In-MINDD tool. Prior to consideration of the findings in relation to the research question and aims, I present a summary of the entire thesis.

In the introductory chapter, I set background for the In-MINDD tool. The focus of the case study was established as an investigation of the requirements development process for the In-MINDD tool. Dementia related risk and protective factors were discussed as core data the system is based on. Chapter 2 to 4 formed the literature review of the thesis. Chapter 2 reviewed literature in the area of eHealth and the barriers and facilitators to the deployment eHealth initiatives such as Personal Healthcare Records. The area of system requirements definition was introduced with regard to defining system requirements in context. Chapter 3 expanded the literature review to include analysis of different approaches to the software development lifecycle and eHealth requirements development. This Chapter appraised the literature on the differing approaches to software and requirements development as influenced by Human Centred Design, service user involvement, Normalisation Process Theory and usability testing.

Chapter 4 discussed the case study methodology adopted and the role of critical realism as a theoretical framework useful for optimizing interventions (Clark et al., 2008). Case study was chosen as a methodology to investigate the dynamics and processes occurring in the specific complex context of primary healthcare with the specific case being the In-MINDD tool. This allowed for the full particularity of the requirements development process for the In-MINDD tool to be analysed with emphasis on stakeholder

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experiences, multiple contexts, issues and questions. Chapter 5 described the research design created for this case study in order to elicit requirements for the In-MINDD tool. Reasoning behind the selection of the In-MINDD tool as the case for study was provided. Research methods identified to gather included interview, focus groups and usability testing. The NPT framework (May et al., 2010) was chosen as a data analysis framework for its power to indicate which stakeholders engaged with the In-MINDD programme and to investigate why engagement was not achieved. I described the process of seeking ethical approval and the considered ethical concerns.

Chapter 6-8 presented the case study findings divided into three phases: Information Gathering, Design in Process and Evaluation. Chapter 6 presented the case study findings of the requirements gathering process for the In-MINDD tool related to the information gathering phase of the research. This Chapter described research carried out with identified stakeholders, investigating stakeholder knowledge, and the processes and communications involved with the In-MINDD tool. Findings indicated that the best way to offer the In-MINDD tool was a stand-alone web based PHR not integrated with primary care systems having a single service user data entry portal. Chapter 7 presented the findings for the Design in Process phase of the case study. Accounts were presented detailing the findings of GP interviews and service user focus groups. Key decisions and changes made to the design of the In-MINDD tool were related. GP concerns were voiced in terms of data entry and increased service user visits. Service user representatives appealed for a support environment that would provide personalised feedback, encouragement and monitoring. Primary Care data sets were found to be of variable quality, providing further reasoning behind offering the In-MINDD tool as a web based PHR for use by the service user. Chapter 8 described findings of usability testing carried out with service users to iteratively evaluate prototypes of the In-MINDD tool. Iterative evaluation through usability testing served to troubleshoot design problems, fix usability issues and fix bugs. Findings from RCT interviews were finally presented to provide feedback with end users on the iterative software development cycle and final version of the prototype design.

This final chapter discusses findings in relation to the research aims and presents conclusions on the research process adopted which may inform future requirements development research on the topic of the development of PHR. Specifically the findings of the case study will be considered in relation to the existing body of knowledge and literature critiqued in Chapters 1-3 and the new knowledge acquired as a consequence of completing this study. The strengths and limitations of this study are reflected upon with recommendations for further iterations of the In-MINDD tool and further research in the related area. An overall conclusion is then presented.

The research question for this study was:

What are the current user requirements in regard to self-care management and prevention strategies in relation to dementia risk and protective factors?

In this chapter I evaluate the extent to which the study has addressed this question and its associated aims. Chapter 6-8 provided a number of specific user requirements in regard to self-care management and prevention strategies in relation to dementia risk. The focus of inquiry for this case study investigated a small sample of key stakeholders and service users therefore findings are not necessarily generalizable to other populations. Conclusions offered should be valued for the insight they can provide to the context of this particular project and for the uniqueness of this study of requirements development for the In-MINDD tool. Stake (1995) calls this particularization as opposed to generalization. Importantly the emphasis here is on reaching deeper understanding of requirements development for the In-MINDD tool as a case and its context which are transferable to other similar contexts. Conclusions should be of interest to research on defining user requirements for the development of PHR and policy makers in the area of self-care management in primary healthcare in Ireland.

This thesis set out to investigate the following research aims:

1. To gain a deeper understanding of the context into which the In-MINDD tool will be implemented and to illustrate this context to key stakeholders engaged with the process of In-MINDD tool design and development.
2. To understand the conditions facilitating the development of user requirements needed to build a personal healthcare record namely the In-MINDD tool from the perspective of two roles namely (a) the healthcare professional and (b) the service user.
3. To explore clinical engagement processes with stakeholders used to elicit requirements.
4. To investigate the most appropriate way to optimise clinical engagement processes with GPs and service users.
5. To optimise the social and technical "fit" between the In-MINDD tool and the existing primary healthcare domain for sustainable impact.

Research aims are expanded upon in sections 9.2 to section 9.6. Initially a short summary is presented of what was known before this case study was carried out on this topic and what is now known as a consequence of completing this study in Table 21 p. 158.

Table 21: New Knowledge Gained following this Case Study

What was Known Before	What is Known Now
In-MINDD algorithm and Functional Requirements were set following the systematic review (Deckers et al., 2015) and Delphi Study see Chapter 1.3.3 p.11.	User Experience and Non-functional requirements have now detailed for the In-MINDD tool see Chapters 6, 7 & 8. Of particular interest to future iterations of the In-MINDD tool and similar interventions aimed at primary healthcare in Ireland. See Appendix K: Requirements Specification Document.
NPT can be employed to identify factors that promote and restrict the routine incorporation of complex interventions into daily practice.	NPT is applicable for requirements development and iterative evaluation of an eHealth intervention. Further analysis is required to investigate reflexive monitoring or appraisal of the tool by service users and GPs following future deployment of later versions of the In-MINDD tool.
CMO configurations (Pawson & Tilley, 1997) can be used to investigate context: A programme works due to the action of some underlying mechanism which only comes into action in particular contexts.	CMO configurations while useful were not as applicable as the NPT framework. It was too early in the project lifespan to accurately view the mechanisms enacted. Part of identified CMO configurations may be more useful as the programme develops as an evaluation mechanism.
There is a movement to equalise the power base in health care delivery. Policy makers are framing service users as consumers rather than recipients. Multiple platforms now allow service users to seek personalised health supports through email, smartphone apps, SMS, GP visits, phone calls. GPs are busy professionals already overburdened with data entry.	A major transition is currently in process for GPs nationally. GPs time and resources are currently limited. Evidence would suggest both from this study and internationally that the service user must be responsible for data entry. Resistance was evident on the part of some GPs to share power with service users indicative of paternalism.
Existing legislative constraints on health information access and use were evident. Data protections legislation limits GP contact with service users to letter, phone call, and face to face visits.	Primary care systems data were found to be of poor quality and variable. Data matching is needed. The enactment of the Health Information Bill and EU directive/legislation on Data Protection anticipated before end of 2015 will address some of these issues. A review of new legislative and governance structures once published is recommended. The protocols for access and interaction with In-MINDD tool should be amended by early 2016. Sufficient data protection legislation is needed before GPs can advance use of ICT with service users as defined in Chapter 9.6 p173-174 recommendations for further research.
In-MINDD Tool will be linked to primary care systems. Clinical staff will be required for registering service user details.	The In-MINDD Tool is a PHR not linked to primary care systems. As a result of concerns over security of service user data and variable engagement with GPs. This led to increased service user control and buy-in. NPT framework can be used to guide the development of requirements, leading to strategic changes to enhance engagement.

9.2: **Context of Use**

This section discusses the context into which the In-MINDD tool was developed for use and explores the following research aim:

(1) To gain a deeper understanding of the context into which the In-MINDD tool will be implemented and to illustrate this context to key stakeholders engaged with the process of In-MINDD tool design and development.

Chapters 2 and 3 explored the impact of context of use on eHealth and PHR technology. A clear understanding of the context into which the In-MINDD tool was designed to sit was sought by the researcher in order to provide optimal implementation and integration following co-design for sustainable use. Context of use for the In-MINDD tool was investigated in Chapters 6-8 and detailed in the UX Specification (Appendix J) and the Requirements Specification documents (Appendix K). The UX specification document gave the In-MINDD partners an overview of approaches to service user recruitment detailing service user interactions during the registration process. The ICT development team used the UX specification document to query and create initial prototypes of the In-MINDD profiler. In addition to contextual factors specified in the UX specification document, the following areas were found to be contextually significant: focusing on the uniqueness of single GP practices; the necessity to provide a web based PHR program for access as opposed to local GP systems; the importance of the registration process with service user control of data entry and the associated dedicated support environment.

9.2.1 Focus on Single GP Practices

The context of primary care in Ireland is complex and this was reflected in the case study. Primary care involves a number of health professionals but GPs are the cornerstone of the system and therefore had a critical impact on the development of requirements for the In-MINDD tool. Conducting this research provided me with first-hand insight into some of the challenges facing the implementation of new eHealth initiatives directed at primary care. Primary care challenges included lack of resources, poor IT infrastructure, need for remuneration, poor access and a lack of efficiencies. A

recurring factor among GPs was an aversion to extra data entry and administration. Access to primary healthcare centres proved difficult to obtain. This is not surprising following many years of significant budget reductions (HSE, 2014), aging demographic profiles (DoH, 2014) and the accompanying increase in demand on the transformation of public health services to meet EU agendas as part of the economic recovery plan (Government of Ireland, 2009). This led to an approach focused on single GP practices, having a direct impact on the choice of research methods specifically using interviews and focus groups rather than primary healthcare team observations. Consequently the researcher suggests that future iterations of the In-MNDD tool and PHR initiatives in Ireland target single practices in addition to primary healthcare centres where possible. GPs play a central role in the health service delivery, engagement with interested GPs willing to drive implementation is significant and must be achieved for strategies aimed at building engaging PHRs for service users in Ireland.

9.2.2 Service User Registration Process

GPs were found to be overburdened with administration tasks and resistant to extra data entry or increased service user visits. Service user registration protocols reflected this finding. The decision was made to have service users responsible for registration data entry. This significantly altered the process of service user registration and gave more control and responsibility to the service user. In order to decrease service user visits GPs advocated for a support environment that was comprehensive and easy to use. Conversely, in partner countries such as France, service user visits resulting from In-MINDD were encouraged by GPs. This shows the cultural difference between the primary healthcare contexts in Ireland and France. It is important for other transnational research in the related area to be aware of these contextual differences.

9.2.3 Web-Based PHR tool

A significant contextual factor was development of the In-MINDD tool as an interoperable web based access PHR that is not bound to particular GP practice management software. This was in part due to variability in the amount of time and data

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entry work GPs were able to give to the In-MINDD project. Service user data security concerns over linking the In-MINDD tool to primary care systems also played a role in the switch to a service user updated tool. This gave greater control and ownership of the tool to the service user. In terms of NPT service user engagement or buy-in was better served in this way. Future versions of In-MINDD will be offered as a PHR web based program applicable to service users regardless of GP practice. In the Irish context this makes In-MINDD more fit for purpose.

Literature reviewed in Chapter 2.3.5 explored the role of the individual as a healthcare consumer that craves more personal control of their health. This case study explored Health Care Professionals that are time poor and resistant to data entry. This research enabled the investigation of requirements elicitation for a new eHealth initiative from a ground up perspective. Findings were consistent with the points considered in Chapter 2.3.5 (p. 28) relating to the development of new eHealth initiatives developed for primary care in Ireland. Development of eHealth/PHR initiatives for primary care use in Ireland need: careful requirements definition in context; location of the service user perspective at the centre of all information systems; be inclusive with representation for both health care professionals and the service user; and give the service user more control of health data.

This provided the scope to reframe requirements and processes according to key stakeholders and end user input. In terms of the core In-MINDD message this case study suggests augmenting the role of the HCP. This research suggests that HCP should not be responsible for service user data entry for new PHR but must be responsible for disseminating the core PHR concept in this case dementia related risk and protective factors to their service users.

9.3: **Non-functional Requirements**

This was a complex study with multiple variables. The process of requirements elicitation is dynamic and therefore constantly changing. The end point of this case study is not the end point of the In-MINDD research. The critical realist sees the end

point as the horizon line which for the researcher means constant horizon scanning to try to anticipate the future for self-care management of dementia related risk factors. The area explored is multi layered, context driven, multi-dimensional and the future is difficult to predict. As the primary healthcare context is continually changing essentially this case study set out to investigate the following research question:

What are the current non-functional and user requirements in regard to self-care management and prevention strategies in relation to dementia risk and protective factors?

In relation to user requirements the most applicable research aim was:

(2) To understand the non-functional requirements needed to build the system from the perspective of two roles namely (a) the healthcare professional and (b) the service user.

The functional requirements for the In-MINDD algorithm were set prior to this case study. The non-functional requirements which are complex have now been detailed in chapters 6-8 and (Appendix K) but are continually evolving and will require reassessment in the future. The focus of inquiry for this research was the user and non-functional requirements specified in chapter 6 - 8. The requirements process followed human centred design principles (ISO, 2010) and PPI agenda (Irish Society for Quality and Safety in Healthcare, 2009) through a process of requirements analysis and system design leading to the building of prototypes by the ICT development team. Paper and software prototypes were tested and iteratively evaluated leading to new iterations based on findings.

9.3.1 <u>GP Data Sets</u>

As a consequence of this research primary care GP data sets were found to be of variable and in some cases poor quality with implications for the accuracy of the In-

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MINDD Tool. More importantly the gaps observed in data sets suggest there may be long term implications for the Individual Health Identifier and future Electronic Patient Record. Future eHealth technologies in Ireland to improve population wellbeing and increase primary care efficiencies need improvements in the quality of primary care data sets. Senior HSE executives such as the Chief Information Officer for the HSE and the associated directorate will need to address this issue going forward.

9.4: **Clinical Engagement**

Clinical engagement and proactive participation with key stakeholders was sought from the earliest stages of this case study consistent with the PPI agenda (Irish Society for Quality and Safety in Healthcare, 2009). The following research aim is discussed here in more detail:

> (4) To investigate the most appropriate way to optimise clinical engagement processes with GPs and service users.

This researcher agrees with Watson (2010) that the implementation of eHealth is time consuming and complex. The NPT framework was found useful to guide inquiry based on clinical engagement and for data analysis for case study findings. The NPT framework provided a clear manner to investigate clinical engagement. The importance of gathering information from a wide array of sources needs to be stressed for future studies of requirements development for PHR in Ireland. As a result of concerns over security of service user data and variable engagement with GPs the In-MINDD Tool was created as a Personal Health Record not linked to primary care systems. This led to increased service user control and buy-in.

An important finding from this research is that the NPT framework can be used to guide the development of requirements providing scope to make strategic changes when necessary to enhance engagement. Future eHealth initiatives should make use of NPT in

order to enhance User Experience and attend to the barriers faced in this research and the innovative solutions created.

NPT was found to be more useful than CMOc (Pawson & Tilley, 1997). Yet as with CMOc, NPT was developed for implementing and evaluating interventions in healthcare and as such is not ideal for early stage requirements analysis research. The NPT framework was designed to evaluate initiatives following deployment. This case study examined the requirements analysis, system design and testing phases of the In-MINDD tool software development not the implementation, deployment and subsequent maintenance involved. Due to this the reflexive monitoring construct of NPT was not applicable for data analysis. As such more research is required to investigate the appraisal of the In-MINDD tool by service users and GPs to investigate clinical engagement using the NPT framework.

9.4.1.a Educational Initiatives Needed

The researcher observed what Stake (2014) would call a tension between the GP, the research team and the service users opinions. It is important to attend to how tensions or differences of opinion affected engagement with the In-MINDD tool design and development. It became apparent that service users, GPs and other stakeholders had a number of differing opinions. Chapter 6 indicated that GPs had concerns for service user safety while some key stakeholders did not agree that there was a demand for In-MINDD from potential service users. An important quote taken from a GP interview described in Chapter 7 was that:

> *"Ideally you don't want to raise a hair if you can't do something about it"*

This quote implies that the GP interviewed doubted whether service users could alter their risk of dementia. The research the In-MINDD concept is based on emphatically rejects this and encourages individuals in mid-life to lead healthy lives in order to decrease dementia risk in later life. More importantly this quote illustrates paternalism on the part of the GP and a reluctance to share power. Potential service users offered different sentiments and were enthusiastic to find out how they can positively affect

their own risk of dementia. A key point here is that service users engaged with the core In-MINDD proposition readily whereas some GPs showed some reticence to the idea. However the topic of dementia causes anxiety for many service users. This indicates that educational initiatives are needed among the general population and among GPs to educate on the link between lifestyle factors and dementia risk in later life. The following quote indicates how a service user felt empowered that by finding out the In-MINDD core message that:

> *"I think that should be emphasized that positivity that if you are managing your heart condition you are also bringing down your dementia risk."*

9.4.1.b Policy Context

The In-MINDD tool is disseminating a complex public health message. Service users need clear, accurate and timely information supported by their GP. It was therefore challenging to endeavour to introduce a novel complex health message in a PHR system to both GPs and service users. Some GP's were more at ease talking to service users about cardiovascular disease risk or cancer risk as opposed to dementia risk.

> *"Patient's understand their heart being protected more so than their brain being protected."*

This gives an indication of how little awareness there is for modifiable and manageable dementia risk factors within general practice in Ireland. The national dementia strategy (2014) encourages targeting dementia risk factors in primary care, however, a disconnect was observed between policy implementation and practice at this time. There is a movement to equalise the power base in health care delivery. Policy makers are framing service users as consumers rather than recipients. Multiple platforms now allow service users to seek personalised health supports through email, smartphone apps, sms, GP visits, phone calls. There was resistance evident on the part of some GPs to share power with service users indicative of some paternalism. There is a tension around providing the service user with access to a complex health message that may not be

easily understood or operationalised. The time taken to investigate context and gather information with multiple stakeholders allowed scope to contextualise these issues. Requirements were elicited and the user interface was designed in order to promote this message in order to make this complex message as easy to understand as possible.

9.4.1.c   *Incentives*

As stated in Chapter 1.2 (p.3) it is currently a time of rapid change in the general practice primary health care domain in Ireland. Recent FEMPI budget reductions have contributed to economic uncertainty and the free GP care for children under 6 contract is set to increase GP workloads (Casey-McGrath, 2015). Future versions of In-MINDD need clinical engagement to advance the In-MINDD programme. In order to engage with over worked GPs it is important to stress the expected benefits such as better quality research based care, enhanced health outcomes and enhanced PHR for service users. Example of these types of demonstrable benefits to service user safety, efficiency and effectiveness (Health and Social Information Centre, 2015b) is the NHS Summary Care Record reviewed in Chapter 2.3.2 p.25. In order to increase the attractiveness and uptake of new technologies in general practice such as In-MINDD, government incentives could be required for new eHealth initiatives. Meaningful use of incentives has proved to be of variable success in the US (Wachter, 2014). If Ireland can learn from challenges encountered in the US Meaningful Use stage 2 it could advance the use of new eHealth initiatives in primary care.

9.5: **Optimising Social and Technical Fit**

Healthcare is changing; service users have more choices and are becoming more involved with their own health through the use of mobile devices. Chapter 1 detailed the how current policy has framed some segments of society as moving from passive healthcare recipients to modern, empowered, proactive healthcare consumers. In order to explore how well the In-MINDD tool fits with the service user and GP the following aim was explored:

(5) To optimise the social and technical "fit" between the In-MINDD tool and the existing primary healthcare domain for sustainable impact.

The In-MINDD tool support environment is limited and personalisation is needed. The version of In-MINDD tool to be redeveloped following the feasibility study has many options. Findings presented in Chapter 7.5.8 indicated service users wanted the support environment to provide personalised consistent feedback. A wicked question this researcher posits:

Is the In-MINDD tool sufficiently mobile, adaptive and interactive?

The current version of the In-MINDD tool is offered as a web page only not a smartphone or tablet application. Producing smartphone or tablet application would make the In-MINDD tool more mobile for service users and for researchers registering new users. Future iterations of the In-MINDD tool could incorporate interactive health data from validated wearable health and fitness devices in addition to the web based program currently offered. This could facilitate additional data collection and improve accuracy of the In-MINDD tool while increasing individual participation with their healthcare plan. Increased granular control could serve to make the In-MINDD tool more attractive to service users. Current GP restrictions in their contact with service users by lack of legislation such as the Health Information Bill 2015 (2015) will also in the short term be addressed.

9.6: **Original Contribution**

This section highlights the original contribution made to the field of engagement processes for user requirements development and addresses the following research aim:

> (3) To explore clinical engagement processes with stakeholders used to elicit requirements.

This research provides evidence that the case study methodology and NPT framework can be complimentary and useful approaches to an investigation of clinical engagement processes during the development of user requirements. The literature review conducted (see Chapter 3.2.8) indicted that NPT had not been used from the outset of an eHealth project previously to guide requirements development as has been done here. The use of

NPT to guide requirements development aimed at clinical engagement processes is, therefore, a new approach and a new way of using the NPT framework.

The NPT framework was used in this study to analyse data gathered, but also from an early information gathering stage in order to structure issue questions, research questions and data gathering questions. As such NPT has been used as an overarching guide to aim requirements development at engagement. This is a new contribution to the field of case study research and user requirements research. The NPT framework has been applied in a new context and from an earlier start point then has been used in previous research. This research indicates that the NPT framework may have further merit in future research applied to user requirements development for eHealth studies. This may be useful for new research on clinical engagement processes for requirements development research in the field PHR development. This confirms the usefulness of NPT and has expanded its application in a new way.

The Context, Mechanism, Outcome configurations (CMOc) framework (Pawson & Tilley, 1997) was tested as a data analysis tool for iterative evaluation of early stage prototypes of the In-MINDD tool. The CMOc framework was not found to be as useful as NPT (May et al., 2010) in terms of data analysis. CMOc may be more useful following programme deployment as the CMOc is a framework developed for evaluation of programmes following implementation. As the In-MINDD RCT progresses there is a need to re-evaluate again using CMOc to investigate what it is about the In-MINDD programme that may result in enhanced service user health outcomes and to investigate the different contexts that will bring about these effects. It is also necessary to investigate the effects of the programme on GP's work and perceptions of service user health outcomes and their accompanying contexts. Therefore, initial analysis while CMO was not found useful in this phase of development but can be used to inform later project development.

9.7: **Recommendations for Further Research**

There are a number of recommendations for future research following this case study. The current version of the In-MINDD tool is being tested with an RCT as part of the In-

MINDD feasibility study. Developers of future iterations of the In-MINDD tool should attend to recommendations mentioned in this section.

9.7.1 Registration Process

The In-MINDD registration process has been identified as having potential for improvement. The In-MINDD profiler in the future could make use of personalised data from smartphones, smart watches and future PHR such as the Apple ResearchKit and Carekit (Apple, 2016). In-MINDD is a modern idea and may be ahead of the curve for general practice in Ireland. Implementation of policy documents such as the national dementia strategy (2014) could lead to more awareness of the modifiable and manageable risk factors for dementia. Systems such as In-MINDD need a careful and measured approach with GP involvement and ownership at the outset. Roles and functions need to be carefully considered based on benefits for GPs and service users. From a critical realist perspective it is important to look to future developments in eHealth and Healthcare in Ireland. There may be opportunity for a future iteration of the In-MINDD tool core resources to be updated through personal health records linked to the service user's individual health identifier and PHR or its associated variants.

9.7.2 Support Environment Personalisation

Chapter 7 and 8 indicated that service users crave individual assessment for tailored health care profiles rather than a one size fits all approach. Email support for service users is currently provided through messages encouraging users to visit the support environment and set goals. Yet all service users receive the same generic email messages. Literature on healthcare consumers suggests that individuals now want more individualised control over their healthcare (Meslin et al., 2013). In order to achieve engagement with future service users this study would recommend that a future version of the In-MINDD tool incorporate personalised email feedback. Personalised email feedback could include emails that encourage service users to target particular risk factors. More personalised supports could utilize data from wearable devices, smartphone or smartwatch apps that collect data on dementia risk factors such as heart rate, pedometer, calories and blood pressure. This research recommends future PHR tools be offered to service users as web based and controlled by the service user.

General practice systems are not appropriate for delivery as the intervention was not a priority for the GP.

9.8: **Limitations of the study**

It is important to attend to the limitations of this case study. Pawson (2014) put it well when he wrote that evaluation studies greatest challenge is complexity. Evaluation studies are beset with the impossibility to cover every angle and to study every issue. From a critical realist standpoint different stakeholder opinions had different levels of importance having different perspectives on one knowable reality. The level of importance of these opinions was attributed by the researcher. Having a different theoretical framework could have led to different findings. As such the current research findings are not universal; rather, they offer one perspective on the development of requirements.

One limitation identified was that of using the NPT framework to iteratively evaluate data during the design of the In-MINDD tool and not when deployed. The NPT framework was designed to evaluate initiatives following deployment. This case study examined the requirements analysis, system design and testing phased of software development not the implementation, deployment and subsequent maintenance involved. Due to this, the reflexive monitoring construct of NPT was not applicable for data analysis. Further research is required to investigate the appraisal of the In-MINDD tool by service users to investigate engagement following deployment. However NPT was useful for guiding requirements development toward enhancing engagement.

This researcher suggests that further research to investigate the implementation, deployment and maintenance phases of software development using NPT of the In-MINDD RCT could provide a more full evaluation of the requirements development research. A further evaluation of the In-MINDD tool in use by service users could serve to further evaluate and validate the tool.

9.9: **Case Study methodology benefits:**

There was a clear benefit to using the case study methodology to investigate the process of clinical engagement during user requirements development. Case study was the overarching methodology setting boundaries in the selection of the case with NPT providing a framework that influenced the formation of issue questions and the analysis of data. As the requirements development process was not pre-specified before the data collection stage of this research a flexible design strategy was deemed most appropriate. Case Study provided a flexible design that evolved during data collection. Ultimately this flexibility led the design of the In-MINDD PHR away from primary care control and to a service user centred and controlled PHR. This was dually beneficial as it led to a PHR offered to the most engaged stakeholder the service user. The service was keen to develop ownership and engagement with their health data. Case Study provided the required flexibility needed to investigate clinical engagement processes during user requirements development from the initial design phase through to the prototype testing phases. The NPT framework was useful for structuring of issue questions toward clinical engagement. Case Study meshes well applied to user requirements development research and is recommend for further research of engagement processes during requirements development.

9.10: **Conclusion**

This case study offered a thorough analysis of the requirements elicitation process for the co-design of the In-MINDD tool. The purpose of this case study was to investigate clinical engagement processes as part of the user requirements elicitation process for a personal healthcare record aimed at health self-management. The Case study methodology and NPT framework can be complimentary and effective approaches in defining user requirements. The support environment was identified as lacking sufficient interactivity needing more personalisation and greater service user interaction. This study presents a novel contribution to the field of requirements development research by investigating the role of engagement processes to specifying user requirements for health software. The NPT framework has been applied in a new context and from an earlier stage then in previous research reviewed. This research indicates that the NPT

framework can help orientate the development of requirements to clinical engagement when employed form an early phase.

Critical factors in this process were found to be optimising clinical and service user engagement, user requirements and the complexity of the primary care context in Ireland. User and Non-Functional requirements and the User Experience have been specified for the In-MINDD tool. User requirements were fit for purpose and aligned well to user experience specifications. The findings indicated a greater demand for this type of intervention among potential service users as opposed to GPs. Following careful consideration of the findings the most appropriate way to offer the In-MINDD tool was as a web based Personal Health Record updated by the service user. This was as a result of concerns over security of service user data and variable engagement with GPs. This led to increased service user control and buy-in.

The NPT framework proved useful to guide the development of requirements providing scope to make strategic changes when necessary to enhance engagement. Future eHealth initiatives should make use of NPT in order to enhance the user experience and attend to the barriers faced to the development of eHealth. The In-MINDD support environment section was identified as lacking sufficient interactivity. More personalisation and greater service user interaction is called for in future iterations of the In-MINDD tool and PHRs and incorporate smart mobile technology to deliver feedback thus supporting personal wellbeing.. Future iterations of the In-MINDD tool could make use of interactive health data from smart, wearable health and fitness devices in addition to the web based program currently offered.

The primary healthcare context in Ireland is already battle weary with data entry and administration. Careful planning is therefore required when implementing a new eHealth initiative. Educational initiatives are needed and called for both in the general population and with GPs on the manageable and modifiable risk and protective factors for dementia in midlife. Existing legislative constraints on health information access and use were evident. The enactment of the Health Information Bill and EU directive/legislation on Data Protection anticipated before end of this 2015 will address

some of these issues. A review of new legislative and governance structures once published is recommended. Following this review the protocols for access and interaction with the next iteration of the In-MINDD tool will prove beneficial for future service users in early 2016. The tensions and barriers described indicate that a move away from this type of purely web based delivery for such a complex health message may be called for. A blended approach combining face to face therapies and web based supports may be more appropriate and worth consideration for future delivery.

Sufficient data protection legislation is called for and will be forthcoming from the European Union. Personal Health Records such as the In-MINDD tool enable service users more control over their health data and could help to reduce the burden on GPs by enhancing health outcomes leading to decreased service user visits. The complexity of service user needs at a population health level demands individualised profiles to be developed for focused and targeted initiatives. More research is needed to investigate the deployment of the In-MINDD tool and to investigate its appraisal by service users and GPs following completion of the In-MINDD Randomised Control Trial.

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Appendices

GP Interview Letter   11/07/2013

Dear _____

Hope you are well. I would like to introduce you to Dr Kate Irving from DCU. Kate is working on an FP7 funded piece of research aimed at increasing awareness of the modifiable risk factors for dementia. The research is aimed at 40-60 year old healthy service users with some of the risk factors (high blood pressure, depression, diabetes, lack of exercise, obesity, smoking) associated with dementia. The system Kate is working on is called the Innovative, Midlife Intervention for Dementia Deterrence (IN-MINDD) and consists of online tools that doctors can use to assess a service user's dementia risk and devise a personalized risk reduction plan.

At the moment the In-MINDD team needs to contact a number of GPs who would be willing to aid with some of the design issues. As the leader of the Work Package defining requirements I would like to recruit 6 GP primary care practises and have each GP recruit 20 service users. This research will require a maximum of 1 to 2 hours per month for 2 months, there will be some reimbursement. This research could serve to benefit patient history records in the future and to spread awareness of the modifiable risk factors for dementia especially in midlife.

Would you be willing to meet with Kate and me to discuss the possibility of participation in the research?

Yours Sincerely

Kevin Power

_____

Appendix B: <u>Phase 2 GP Interview Recruitment Letter</u>

Dr…………..

In-MINDD Research Team9th January 2014

Re: Invitation to participate in research on the co-design of In-MINDD

Dear Dr. ……….,

We are writing to invite you to participate in research to inform the development of an online brain health profiler for individuals in mid-life (40-60 years). The project will also develop personalised strategies to reduce risks to participants' future cognitive health and develop a supportive online environment to help individuals follow their personal strategy. This research is part of a European funded project (In-MINDD FP7/2007-2013) led by Dr. Kate Irving, School of Nursing & Human Sciences in Dublin City University.

There is now compelling evidence that dementia can be delayed by lifestyle changes in midlife. Given the huge social and economic costs of dementia, even a delay of one year would make such interventions cost effective. Since GPs are uniquely positioned to promote the health of their service users, we are seeking to recruit a small number of GPs willing to provide us with their views about and some feedback on the In-MINDD online tool and its online support environment, which is currently in development. If interested, you will be asked to participate in one interview, which will last for no longer than one hour and take place at a time and place that is convenient to you. You will also be asked to identify 6 to 8 service users attending your practice with one or more of the following risk factors: Depression, Diabetes, High Cholesterol, Smoking, Alcohol, Obesity, Heart Disease, Hypertension or Cognitive and Physical inactivity and who

would be willing to give their views on the In-MINND online tool and supportive environment through participation in a focus group, which will be organised and facilitated by the research team. In recognition of time and other commitments of GPs participating in this research, we are offering a payment of €500 to cover costs incurred. GPs participating in the research will be invited to be an author on any journal articles emerging from this research.

A second phase of the research involving a feasibility (RCT) study of the In-MINDD profiler and environment in practice in Ireland and three other partner countries will commence in mid-2014. GPs and service users participating in the co-design of the In-MINND online tool will be eligible to participate in the feasibility study. Please find enclosed a plain language statement. If you would like any further information about this research and are interested in taking part please contact Kevin Power on: 086 1955497or 01 7006866 or alternatively email: kevin.power9@mail.dcu.ie. You can also find more information on the study at: http://www.inmindd.eu/

Yours sincerely,

Appendix C: <u>GP Interview Information Sheet</u>

Research Study Title: Co-design of the In-MINDD cognitive brain health profiler and supportive environment (GP)

About the study

The INMINDD project, funded by the European Union (In-MINDD FP7/2009-2013), is developing an online brain health profiler to assess the risk of individuals in mid-life (40-60 years) of developing dementia in later life and provide a personalised action plan of ways to reduce this risk. This research adopts a case study approach to investigate the development of the In-MINDD online tool and its use in practice. A key part of this research is to engage with GPs and their service users and get feedback from them as potential end-users of the In-MINDD online profiler. The feedback will be used to inform the future development of the In-MINDD profiler.

I, Kevin Power am a PhD student, and the research is being undertaken as part of my PhD study. Dr Pamela Hussey and Dr Kate Irving are my academic supervisors and the results of this research will be written up as a doctoral thesis.

The Research Team also includes:

Dr. Kate Irving (Lead Investigator)

Dr. Maria Pierce (Postdoctoral Researcher)

Ms. Muriel Redmond (Research Assistant)

What does taking part involve?

If interested, you will be asked to participate in one interview, which will last for no longer than one hour and take place at a time and place that is convenient to you. During the interview you will be given a demonstration of the online In-MINDD system and asked to offer your views and opinions on its design, content and use. With your consent the interview will be audio recorded. You will also be asked to identify 6 to 8 service users attending your practice with one or more of the following risk factors: Depression, Diabetes, High Cholesterol, Smoking, Alcohol, Obesity, Heart Disease, Hypertension, Cognitive or Physical inactivity and who would be willing to give their views on the In-MINND online tool and supportive environment through participation in a focus group, which will be organised and facilitated by the research team.

What else do you need to know?

A payment of €500 will be made to your practice in recognition of the time taken to assist with the research. Potential benefits to participating GP practices include: being informed about lifestyle changes that service users can take to help delay the onset of dementia and an opportunity to contribute to the development of an online dementia risk analysis and reduction system. There are no risks to GPs or their practices participating in the study.

Confidentiality:

The following measures will be adopted to ensure the confidentiality of GPs and GP practices participating in the research is safeguarded:

- Audio recorded interviews will be transcribed. Recorded material will be anonymised and transferred to a password encrypted database for storage and retrieval.

- Only those working on the research team, and named below, will have access to audio recorded material and transcripts of the interviews, for the sole purpose of analysing the data.
- Signed consent forms will be stored in a locked filing cabinet and will not carry any information or identifying codes that connect individuals to specific recorded data.
- All documents will be anonymised to ensure that an individual GP or GP practice cannot be identified.

This study has been granted approval by the DCU research ethics committee.

Contact Details:

If you are interested in participating or would like to ask any questions, please contact Kevin Power by Mobile: 086 1955497, Office +353 1 700 6866 or by email: kevin.power9@mail.dcu.ie.

Alternatively, you can contact:

Dr Maria Pierce (Postdoctoral Fellow) by telephone +353 1 7006084 or email: Maria.Pierce@dcu.ie.

Dr Kate Irving (Project Lead and Academic Supervisor) by telephone +353 1 700 7985 or email: kate.irving@dcu.ie. Muriel Redmond (Research Assistant) can be contacted by telephone +353 1 700 8034 or email: muriel.redmond@dcu.ie

Appendix D: <u>GP Interview Consent Form</u>

Co-design of the In-MINDD cognitive brain health profiler and support environment (GP)

CONSENT FORM

This form has been drawn up to ensure that you have been fully informed about the study and have given your consent to take part in it. Please read the following before you sign the form:

- I have read the information sheet
- I know what the study is about
- I know what taking part will involve
- I know that I do not have to take part in the study
- I know that I can withdraw from the study at any time and I do not have to say why
- I have the opportunity to ask questions and discuss the study and have received satisfactory answers to my questions
- I understand that I can refuse to have my interview with the researcher audio-taped
- I understand that the interviewer may write about what I say

- I understand that everything I say will be treated as strictly confidential and my name will not appear on any publications emerging from the research

Your name: _____

Your signature:_____

Today's date:_____

GP interview topic schedule

Topic 1: General Knowledge of, attitudes to and current practice regarding dementia deterrence

Q. What kind of knowledge do you have about risk factors for dementia and prevention of dementia?

Q. What advice, if any, do you currently offer to service users who present with risk factors for dementia?

Q. The overall aim of the In-MINDD project is to help prevent or delay the onset of dementia by encouraging adults in midlife to adopt more healthy lifestyles. How valuable do you think interventions to reduce risk of dementia risk are?

Topic 2: In-MINDD

Identification and recruitment of potential service users

Profiler Content questions (where applicable will be sent in advance to GP)

These are the type of questions the profiler will ask. Have you any views on them?

We are particularly interested in talking to you about the clinical information required for the In-MINDD profiler: relating to the following:

- BMI (Height/weight)
- Total cholesterol and medication for high cholesterol
- Cardiovascular/heart disease
- Blood pressure levels and medication for hypertension
- Diabetes mellitus
- Chronic kidney disease
- Family history of dementia and cardiovascular disease.

Would you know anything about your service users' levels of cognitive inactivity or physical inactivity?

Q. Would you generally have information on each of the above for service users in midlife?
The intention is that service users will input the data into the profiler. However, they may not have or know their cholesterol levels or blood pressure. In that case, would your preference be for:

- the GP to input this information, where available, for each participating service user into the profiler

or

- the service user to be given this information, where available, by their GP, for example, via a hard copy information sheet provided by the research In-MINDD team and completed by the GP?

Q. What approach do you generally use with regard to communicating with your service users? Are all your meetings face-to-face or would you communicate by email, phone or text with your service users?

Topic 3: Dementia Risk Score

Different ways of presenting DRS

Feeding back DRS to service users; Role of GP in communicating and interpreting this information

Topic 4: Personalised plan and supportive environment

Personalised plan and approval of it by GPs and discussion with service users

Supportive environment and example of physical exercise information that will be provided to service users using the In-MINDD supportive environment
Q. What, if any, websites/online supports do you currently direct your service users?
Q. Are there any other supports/services that we could make In-MINDD users   aware of?
Q. Would you like to see this information presented differently?

Still teasing out other kinds of supports (via social media) that we can offer through an online environment

Supporting service users: realistically how much involvement can the GP have? How much feedback, if any, would you like to receive feedback about your service users' progress with In-MINDD

Supporting GPs: How useful do you think this supportive environment will be to you in supporting service users to reduce their risk of dementia? What other supports might GPs need?

Appendix F: Focus Group Information Sheet

PARTICIPANT INFORMATION SHEET

Study Title: In-MINDD **:** INnovative, Midlife INtervention for Dementia Deterrence

You are being invited to take part in a focus group in DCU. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take some time to read the following information and discuss it with others if you wish. If there is anything that is unclear, or if you would like some more information, please feel free to contact us. Thank you for taking the time to read this.

We would like you to consider helping us with a research study looking at how we can potentially reduce the risk of developing dementia. In order to do this we are running a trial comparing an online dementia risk assessment and internet based support system, referred to as In-MINDD, with routine practice for people aged 40–60 years in the primary care setting. We would very much appreciate your help with this. The project is led by Dr Kate Irving, School of Nursing and Human Sciences, Dublin City University.

Why is the study being done?
There is evidence that addressing factors such as high blood pressure, obesity, smoking, physical and social inactivity in midlife can improve your chances of avoiding or delaying dementia. The aim of the In-MINDD study is to use this information to help adults to adopt lifestyle changes that may reduce their chance of developing dementia, or delay its onset.

Why have you chosen me?

You have been approached because you are aged between 40 and 60 and have one or more of the potential risk factors and are registered with a GP practice that is helping with this study.

Do I have to take part?
No, it is up to you to decide whether or not to take part. Your decision will not in any way affect the care that you receive. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. Even if you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the care that you receive.

What will I have to do if I take part?

If interested, you will be asked to participate in one focus group interview, which will last for no longer than two hours. Prior to the focus group you will be asked to fill out a short questionnaire about your level of IT usage. During the focus group you will be given a demonstration of the online In-MINDD system and asked to offer your views and opinions on its design, content and use. The focus group will be attended by approximately 6 to 8 individuals that attend the same GP practice as you. We would also

like to know if you have any experience of using online resources for health promotion and how beneficial you think these are. Focus groups will be held in a quiet, room in DCU with refreshments provided at a time agreed between you and the researcher. You may be asked to take part in a follow-up focus group lasting no longer than one hour at a time agreed by you and the researcher in the future.

What are the possible disadvantages of taking part?
If you decide to take part in the study you will be talking about the risk of developing dementia in the future. Some people worry about the possibility of developing dementia and these discussions may bring such concerns to the fore. You are free to ask the researcher to move on to another topic at any time. If you wish to withdraw from the focus group at any time you are free to do so and do not have to give a reason for your withdrawal. We can direct you to online supports which can offer you support if you are concerned about the risk of developing dementia.

What are the possible benefits of taking part?
The aim of the In-MINDD study is to reach potential future patients when they are in mid-life and help them adopt lifestyle changes that may reduce their risk of developing dementia, or delay its onset. Taking part in this study will make you aware of what puts people at risk of developing dementia and what actions can be taken to maintain a healthy brain. Your participation will contribute to the design of the In-MINDD tool. No payments are available for taking part in this study.

Will my taking part in this study be kept confidential?
Everything you tell us will be **strictly confidential**. Any information held on computer will be password protected and written notes will be stored securely in locked filing cabinets in the School of Nursing and Human Sciences in Dublin City University. The information will only be available to the research team and interview transcripts will be anonymised. The files will be destroyed ten years after the study is complete. Anonymised information will be archived and may be used in future research. We may use quotes from interviews, but we will ensure that any identifying information will be removed. In exceptional circumstances it may be necessary to break confidentiality for legal reasons.

What if I have a complaint?
If you should wish to complain about this study please feel free to contact Dr Kate Irving (Tel: 01 700 7985; Email: kate.irving@dcu.ie). If you have concerns about this study and wish to contact an independent person, please contact: The Secretary, Dublin City University Research Ethics Committee, c/o Research and Innovation. Support, Dublin City University, Dublin 9. Tel 01-7008000

What will happen to the results of the research study?
We intend to write up our findings in reports and papers for peer-reviewed journals. We would like to assure you that your experiences and opinions will **not** be traceable back to you in any of our publications, and your information will be combined with that of other service users' so that you will not be identified in any way.

Involvement of the General Practitioner / Family doctor (GP)
Your GP will be aware that you are taking part in the focus group, because we are working in partnership with your GP practice. This will not affect your care in anyway. Your doctors and nurses will not know what you have said to us.

Who is funding this research?

The In-MINDD project is funded by the European Union Framework Seven Programme (FP7/2007-2013) under grant agreement No. 304979 ('In-MINDD').

There is no commercial sponsorship of this study.

Who has reviewed this research?

This study has been reviewed by and granted approval by the DCU Research Ethics Committee and the Irish College of General Practitioners Research Ethics Committee. It has also been approved by the HSE National Primary Care Research Committee.

Who are the research team?

The research is being undertaken by researchers across four countries at Dublin City University, University of Glasgow, Maastricht University and Université de Nice Sophia Antipolis. The researchers for the project in the School of Nursing and Human Sciences, Dublin City University are:

Dr Kate Irving, In-MINDD Project Co-ordinator and lecturer in mental health nursing (Tel: 01 700 7985; Email: kate.irving@dcu.ie.

Dr Maria Pierce (In-MINDD trial co-ordinator (DCU) and researcher (Tel: 01 7006084; Email: Maria.Pierce@dcu.ie).

Muriel Redmond, researcher (Tel: 01 700 8034; Email: muriel.redmond@dcu.ie).

Kevin Power, PhD student (Tel: 01 700 6866; Email: kevin.power9@mail.dcu.ie).

You will be able to find out more about the study by contacting the researchers above.

If you have concerns about this study and wish to contact an independent person, please contact:

The Secretary, Dublin City University Research Ethics Committee, c/o Research and Innovation Support, Dublin City University, Dublin 9. Tel 01-7008000

Thank you very much for considering taking part in our research. Please discuss this information with your friends, family or doctor if you wish.

Participant Identification Number:_____

CONSENT FORM

Title of Project: Co-design of the In-MINDD cognitive brain health profiler and supportive environment

Name of Researchers: Kevin Power

Please tick box

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that this study consists of engaging with an online dementia risk reduction programme and taking part in an interview about the programme which will be audio-taped. Interviews will be treated with confidentiality and none of the information from the In-MINDD system or interviews will be traceable back to me. ☐

3. I understand that all personal identifying data will held securely for a period of up to ten years. ☐

4. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

☐

5. I understand that data collected during the study will be used by researchers involved in the study and anonymised data may be archived and used in future research.

☐

6. I understand that individuals from the research team will have access to my name, address, date of birth, and telephone number, and that regulatory bodies auditing the conduct of this research may also have access to this information, for up to 5 years after the study has finished. I understand that this information will be stored securely and treated confidentially. I give permission for these individuals to have access to this information.

☐

7. I agree to take part in the above study.

☐

_____   _____   _____

Name of participant   Date   Signature

_____   _____   _____

Researcher   Date   Signature

Appendix H: <u>Focus Group Script</u>

Service user In-MINDD Co-Design Focus Group Script – 13/5/2014

Good evening, thanks for agreeing to participate in this research. I am Kevin Power. I am a full time PhD researcher here in DCU. This research is concerned with your thoughts and opinions on a number of issues related to the In-MINDD brain health program.

In-MINDD is an EU funded project with a team of researchers in DCU, Scotland, France and the Netherlands. Over the past year and a half this project has been investigating the lifestyle factors that promote brain health and can lead to a reduced risk of developing dementia. Using this information, the research team are developing an online system to assess individual's in mid-life to see if they have a lifestyle that supports brain health and to offer them a personalised strategy and online support system to help them adopt a brain healthy lifestyle. This in turn may help people to reduce their risk of developing dementia in later life.

So far we have had a number of interviews with GPs who have given us some feedback on the system and it is important for us now to get feedback from people who could potentially be using the system.

I have asked you here today to gain some input from your experiences and opinions on the subjects of Brain Health, Dementia, and the use of web based programs to promote a healthy lifestyle to promote brain health. You will also be shown some examples of the assessment tool and support materials and asked for your thoughts and opinions. There are no right or wrong answers and all comments are valid.

My role today is one of researcher/facilitator for this group discussion. It will last for approximately 2 hours.

Introduce assistant – I will be assisted by Muriel Redmond, Research Assistant.

The order of the meeting is as follows

Short introduction about the meeting and what today is all about

Some housekeeping details – timing, one person speaking at a time.

Filling in of CONSENT forms

Then we will start the discussion

I will then close the session at approximately 8.30 p.m.

I will keep the session as informal as possible.

Is there anything about the format of this focus group interview you would like clarification on?

Before we begin can I say that it is important to ensure that you are fully informed about the research and what participation in the study involves, and the data collected today is with your full permission. Consequently I would ask you all to sign the consent forms that I have here.   There are two copies – one for your own records and one to be handed back to me as researcher.

On the form you will see that I am also requesting that this interview be recorded. This is to ensure that I can give you my full attention instead of taking copious notes, It will also capture what you say accurately and therefore will also facilitate with further analysis by me and the research team.

5. Ice breaker

- What kinds of leisure activities or hobbies to do you take part in your spare time?
  Exercise, Gym, Sports, Swimming, walking. Play musical instrument, socializing, attending cinema, theatre,

6. Awareness and knowledge of dementia, risk factors for dementia, and lifestyle for brain health

- How much do you know about dementia? What do you think about it?

- Age and genetics can play a role in the development of dementia. Do you know what lifestyle factors play a role in the development of dementia?
- Where did you come about this information?
- Would you be interested in knowing more about lifestyle factors associated with dementia?
- What would you like to know?
- Do you know what steps you can take to protect your brain health?
- Prompt: Weight management, Healthy Eating, Exercise, Socializing

7. Introduction Video

I am now going to play a video that I created to explain In-MINDD. Please watch and let me know what you think afterwards.

- Can you tell me what you think about the video?
- Do you have any questions about the video?
- Does it make sense to you?
- Are there any points that were not clear or easy to understand?
- What would you expect from a system like this?

8. Profiler Screen Shots

I am now going to present some screen shots from the In-MINDD profiler. The profiler is based on the most current research on brain health. When an individual fills out the profiler In-MINDD will give the user a brain health score and personalised plan of ways to improve brain health. Please comment on the screen shots with any thoughts that occur to you.

- Have you used programs/apps like this before?
- Is the information easy to understand?
- Would you have this kind of information (BMI,blood pressure,Cholestrol, weight, height) to hand at home?

- Would you prefer your GP to give you these clinical information or for the GP to give   them directly to a researcher?

9. Brain Health (LIBRA – Life Style Improvement for Brain Health) Score
- I am now going to present some brain health score examples from the In-MINDD   profiler.
- Does this make sense to you?
- Do you like the way the information is presented?
- Would you like to see this information presented in a different way?
- If so How?

10. Supportive Environment

The supportive environment will offer the individual personalised information on ways to improve their brain health. This will be in the form of websites that will aid specific goals such as weight loss or stopping smoking. This will also include forums where individuals get feedback from experts in specific area e.g. health, nutrition, smoking cessation.
- How would you feel about communicating with other users via an online forum such as Facebook?
- I will now show you some examples of the supportive environment resources such as websites.
- Have you used any of these websites before?
- Why do you use/ or not use these types of websites?
- Do you have any opinions on these types of website?
- What motivates people to keep using a program like this?
- Do you think you would use In-MINDD for 6 months?
- What kinds of support would you need to use this system?
- How would you like to be contacted if you were to use this tool by email, text or phone call?
- Would you meet with your GP to discuss the plan?

- Would a help section be useful?

- What kinds of things would you like to see in this section?

11. As In-MINDD is an online tool it is important for us to know a bit about your access to and experience using the internet

- Could you tell me about your access to the internet at home or elsewhere on a day to day basis?

- Would you be in a position to use the internet or computer to use a system like In-MINDD?

- Do you think there are any barriers to you?

- What is your experience of using, if any, of web-based health programs?

- Prompt: Weight management, Healthy Eating, Exercise, Socializing

- What do you think of web based programs or interventions for improving your health?

- Do you have wifi internet at home?

- Would you be able to fill this out at home? Would you like to fill this out in DCU?

12. Finishing Statements

- Considering what you have heard how do you feel now about the lifestyle factors associated with dementia?

CONSENT FORM

Title of Project: Co-design of the In-MINDD cognitive brain health profiler and supportive environment

Name of Researchers: Kevin Power

Please tick box

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that this study consists of engaging with an online dementia risk reduction programme and taking part in a usability test using the In-MINDDD program which will be audio-taped. Information inputted into the In-MINDD system will be treated with confidentiality and none of the information from the In-MINDD system will be traceable back to me.

3. I understand that all personal identifying data will held securely for a period of up to ten years.

4. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

5. I understand that data collected during the study will be used by researchers involved in the study and anonymised data may be archived and used in future research.

6. I understand that individuals from the research team will have access to my name, address, date of birth, and telephone number, details of my current medical conditions and medications, and that regulatory bodies auditing the conduct of this research may also have access to this information, for up to 5 years after the study has finished. I understand that this information will be stored securely and treated confidentially. I give permission for these individuals to have access to this information.

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7. **I agree to take part in the above study.**

<div style="border: 1px solid black; width: 50px; height: 50px;"></div>

_____   _____   _____

Name of participant   Date   Signature

_____   _____   _____

Researcher   Date   Signature

Appendix I: <u>Usability Test Script</u>

Usability Test Script

Note: In-MINDD should be open on login/register page.

Hi, _____. My name is Kevin Power, and I'm going to be walking you through this session today.

Before we begin, I have some information for you. You probably already have a good idea of why we asked you here, but let me go over it again briefly. We're asking people to try using the In-MINDD program that we're working on so we can see whether it works as intended. The session should take about 30 minutes. The first thing I want to make clear right away is that we're testing the site, not you. You can't do anything wrong here.

As you use the program, I'm going to ask you as much as possible to try to think out loud: to say what you're looking at, what you're trying to do, and what you're thinking. This will be very helpful for us. Please give your honest reactions to the program.

If you have any questions as we go along, just ask them. I may not be able to answer them right away, since we're interested in how people do when they don't have someone sitting next to them to help. But if you still have any questions when we're done I'll try to answer them then. And if you need to take a break at any point, just let me know.

I'm going to ask you to sign a consent form, by signing you consent to take part in the usability testing.

Give participant consent form and a pen.

Do you have any questions so far?

OK, great. Let's begin.

Login/Register page

Please register with this_____ number. Password is _____.

Please follow the prompts and ask me if you need help on where to go next.

Scenario 1

Please update information for all sections of the profiler ask me if you have any queries. When you are finished each section click submit.

Scenario 2

Please view your LIBRA score and please speak aloud your thoughts as they occur to you. Feel free to click around on any images or icons that interest you.

Do you have any questions for me, now that we're done?

Stop the screen recorder and save the file.

Thank participant and escort them out.

INMINDD User Experience Specification V2

This document presents a proposed user experience walkthrough from the perspective of the service user. The service user's interaction with the In-MINDD tool is best understood as a process. This process is detailed below with the aid of diagrams, use case scenarios and data flow diagrams. Unified modelling language (UML) is used to outline the data flow through the different In-MINDD phases. This exercise is carried out in order to accurately give an overview of the intervention. The primary healthcare team (PHT) that will interact with In-MINDD may include a GP, a practice nurse, receptionist or other allied health professional. The actors involved in the following user experience walkthroughs include:

- Primary healthcare team: Clinician
- In-MINDD Researcher
- Service user: Client or user

User Persona and Experiences

A user persona was created to facilitate the user walkthrough. A user persona is a fictional example of an individual who expresses an interest in and is eligible to use INMINDD. The user persona created is referred to as Client A. It will be necessary to create other user personas at a later date. Different user personas can help with working through the user experience from different perspectives such as a client who is ineligible to participate.

Phase 1: Proposed Recruitment Approach

Client A is a 49 year old, male, mature student. The client is a smoker (10-15 a day), drinks occasionally, has moderate to high blood pressure and gets little exercise. The client has experience of dementia through a close family relative. The client visits the GP for a regular check-up. Client A enters the practice and lets the receptionist know

that he has an appointment with the GP. Three different recruitment scenarios are proposed:

Recruitment Scenario 1 ad hoc:
While in the waiting room the client sees an INMINDD brochure/poster. Client A asks a member of the primary healthcare team for more information on INMINDD. Alternatively the client takes an INMINDD brochure away to read.

Recruitment Scenario 2 active GP recruitment:
The GP actively recruits service users during a GP visit. During a consultation the GP asks the client if they would like to be involved in the INMINDD project. The service user is given an information pack and plain language statement and asked to take this home and review.

Recruitment Scenario 3 mail shot:
The GP picks a number of service users to be contacted by the INMINDD research team. The GP picks service users who fit the eligibility criteria. Service users on the mailing list are sent an information pack and a plain language statement.

The INMINDD information pack materials should:
- Inform the client of the INMINDD project, (containing flyers, brochures and links to the INMINDD website)
- Provide some educational information on risk of developing dementia (e.g. dementia risk factors modified in midlife can decrease chances of dementia in later life).
- Inform the client of the eligibility criteria (see below). This may help to rule out clients who are ineligible to participate.
- Provide contact details of the INMINDD researcher whom the client can contact directly to express an interest in participation

- State that participation is only available to service users of the practices registered with In-MINDD (i.e. friends or relatives should not call the INMINDD researcher unless they attend the same practice).

Table 1. Eligibility Criteria

Service user Inclusion Criteria	Service user Exclusion Criteria
Age:40-60	Aged under 40 or over 60
No mental Health Problems	Recognised mental health problem
No Cognitive Impairments	Cognitively impaired
Able and willing to give informed consent	Unable or unwilling to take part in the research
Established clients with the GP 12 months	Client with the GP less than 12 months
Have at least 1 of the risk factors associated with dementia risk.	No factors associated with dementia risk.

Table 1. Eligibility Criteria

The clinician will ask the client for permission to pass on contact details (a phone number/email address) to the INMINDD researcher. Alternatively the clinician will ask if the client would like to be contacted by the INMINDD researcher. If the client consents to being contacted by the researcher the clinician will contact the researcher by email/phone to alert them to an interested client. The client should be given time (2-5 days) to review this information. Following this review period the researcher will contact the client by phone/email to establish if they are still interested, if there are any questions that they would like answered and if they would like to proceed to the enrolment stage.

Phase 2: Enrolment meeting

Some consideration needs to be given to the process of enrolling/registering clients with In-MINDD and how this will be done, through a face-to face meeting with researcher or nominated member of the PCT. At this time the following is proposed:

At this stage Client A has been in contact with the researcher, an interest has been expressed and a meeting has been arranged. A meeting is arranged in the primary healthcare centre at a time that suits both parties. Alternatively a meeting may be arranged at a secure location agreed upon by both researcher and client. The researcher greets client A, checks again that the client is eligible to participate in In-MINDD, and explains in detail what the purpose of INMINDD is and what participation will involve. The researcher makes sure to answer any questions the client may have regarding participation. The researcher will then help Client A to complete the core resources. The core resources needed by the researcher during this recruitment session include:

1. Eligibility document (taken from the participant inclusion, exclusion criteria).
2. Plain Language statement
3. Informed Consent Form
4. Educational materials (could include examples of the INMINDD interface, how to navigate INMINDD, a short video tutorial, website, brochure which may be delivered on a laptop or tablet).

This enrolment session is of particular importance. Eligibility for participation should be determined quickly so as not to waste the time of both parties. This process is completed in partnership with the client and researcher rather than an independent process. This will enable the client to ask questions just in time. The researcher is responsible for the development of a trust relationship between participant and researcher. The participant should be sufficiently educated on INMINDD to promote the best chance of completion. The client should have further time to consider participation if required. However

minimal time should be taken (where possible between the information session and completion of informed consent.

Phase 3: Participant Registration Process

When all mandatory core resources are complete the researcher will help client A register with the INMINDD tool. The client will enter some demographic information such as (age, sex, name, address).The system will automatically assign Client A with a personal username and password which the client will later use to access the online INMINDD portal at home. The system will assign the client a unique INMINDD client code that will be matched to the unique health identifier. The IMINDD client code is encrypted and password protected. The researcher can later use this code to update clinical information on behalf of the client. This signals the end of the registration phase.

Phase 3: INMINDD Clinical Data Portal

Proposed Scenario

The researcher will give a hard copy clinical information sheet to the GP. The clinical information sheets will be named with the unique INMINDD client code. The information sheet will contain the clinical inputs (BMI, cholesterol, blood pressure). The GP will update the hard copy with the clinical inputs. The researcher will take the hard copy and update the clinical portal (soft copy) with this information. When the researcher has updated the clinical portal the hard copy will be destroyed. Below is a screenshot presenting the clinical inputs of the prototype INMINDD profiler.

Profiler Details

Patient Information	Patient Feelings	Physical Activities	Social Activities

Clinician Input

Input BMI

Input Total Cholesterol Level (mmols)

Input LDL Cholesterol Level (mmols)

Input HDL Cholesterol Level (mmols)

Input Systolic Blood pressure

Input Diastolic Blood Pressure

Previous Page

Clinical Inputs

Alternative scenarios based on partner comments

Scenario 1

> **Step 1:** The clinician provides the participant with a hard copy report specifying the clinical data required (e.g. BMI, Cholesterol, Blood Pressure etc.).
>
> **Step 2:** The participant takes the information and uses it to complete the clinical part of In-MINDD online questionnaire via self-report portal. With this scenario there would be no clinician portal.

Scenario 2

> **Step 1:** The clinician provides the In-MINDD researcher with a hard copy report specifying the clinical data required (e.g. BMI, Cholesterol, Blood Pressure etc.).
>
> **Step 2:** The In-MINDD researcher takes the information and uses it to complete the In-MINDD online questionnaire via clinical portal. With this scenario a clinical portal would still exist, but would be completed by researcher with no such role for clinician.

Phase 4: INMINDD Participant Self-report data Portal

Client A will input data into the self-report portal online. The researcher will be available to address any troubleshooting issues or queries that this client may have. The client will be given a phone number/email address of the researcher with contact details of the researcher. Client A will login to INMINDD using his username and password. The service user will update information under a number of categories including: service user information, service user feelings, physical activities, social activities, family medical history, alcohol intake and smoking. The service user will be asked to complete the self-report in one week from the time consent is given. The self-report portal will be paired down, quick to complete and all fields will be mandatory.

Phase 5: Service user Risk Reduction plan and approval process

When both the clinical and self-report portals are completed the client's dementia risk score and personalized risk reduction plan will be generated and sent to the researcher. The researcher will schedule a weekly half hour meeting with the GP. During this meeting the researcher will present the service user risk reduction plans to the GP. If the GP does not approve a plan the plan will be altered or removed. The researcher will alter the plan to comply with the GPs recommendations.
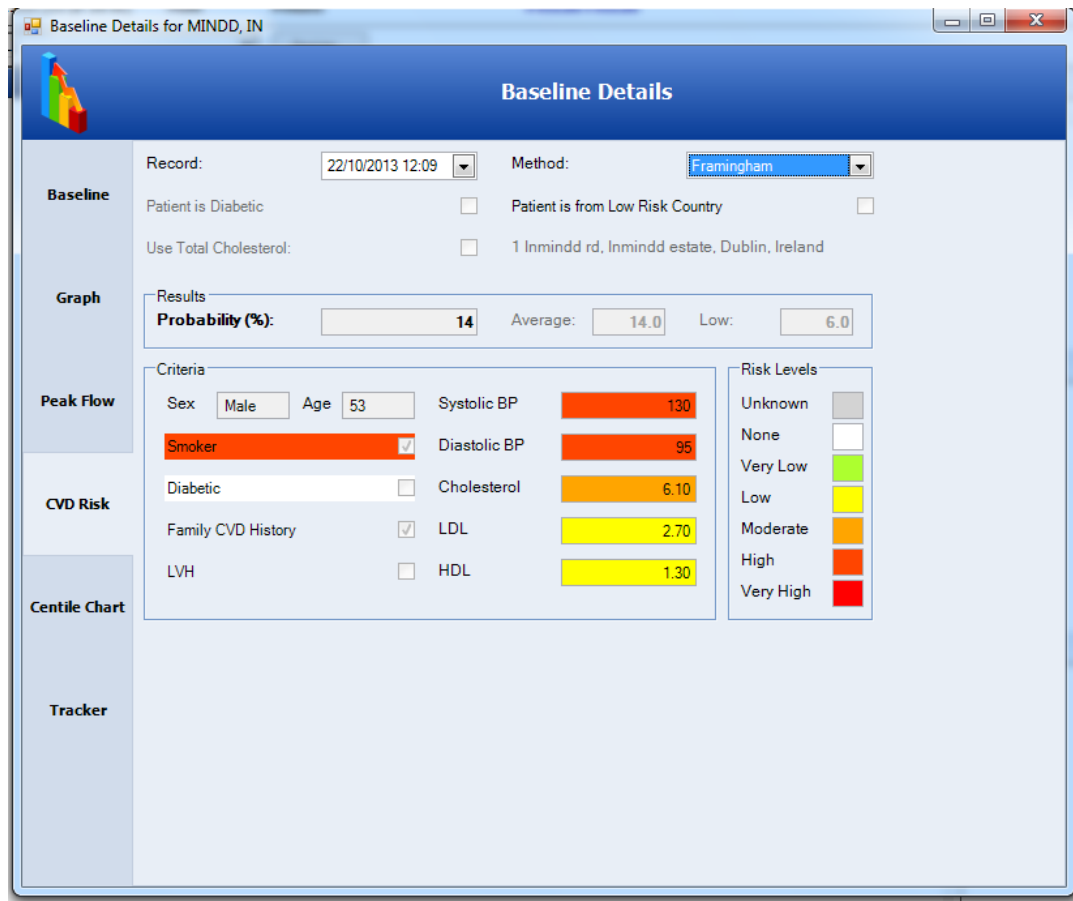
Altering a plan

For instance in the case of a client that has a heart condition. INMINDD may suggest participation in a fitness program. The GP may say this is undesirable. The researcher may substitute a physical fitness program for an improved diet, reduced alcohol intake or smoking cessation service. The GP must then review this risk reduction plan in the next meeting.

When GP approval has been received the researcher will discuss the plan with the client. The researcher will discuss the graphs/outputs within the produced from the dementia risk score which will be entitled room for improvement or change. The Framingham health cardiovascular risk output (see below) provides an example of how to structure a risk score. Some further consideration needs to be given to this phase and to issues such as:

Do GP and practice nurse require training around this and how much and how is that training to be delivered?
Who should be involved in this phase and what are their respective roles?

Framingham health Cardiovascular Risk Calculator Screenshot

Phase 6: Profiler and supportive environments

Participant is notified and goes online to access relevant websites, forums and supportive environment

Issues that arise in this step include governance and data control issues

- Selection and suitability of websites
- Who will be nominated to monitor and moderate the material posted on online forum and be accountable for it?
- Are experts available for consultation, if needed
- 3 month follow up online
- 6 month GP follow up needed to retest clinical measure

Client A will then be asked to use the INMINDD self-report portal. Client A will login to INMINDD using his username and password. Using the self-report portal Client A can:

- Update relevant information which was not updated with the researcher in the clinical portal. Questions around timing: Is this random update or is there a timeframe i.e. must be completed monthly. How often is data updated and why?
- Access dementia risk reduction score.
- View personalized risk reduction strategy.
- Access web based services specifically related to reduction strategy.
- Access forums where to enter a supportive environments related to personal risk reduction strategy.

Focus group interviews with over 50s may be useful to tease out the emerging issues outlined above would be a useful exercise. For example, the focus group could be used to determine what they would be comfortable with as mandatory fields in the self-report portal.
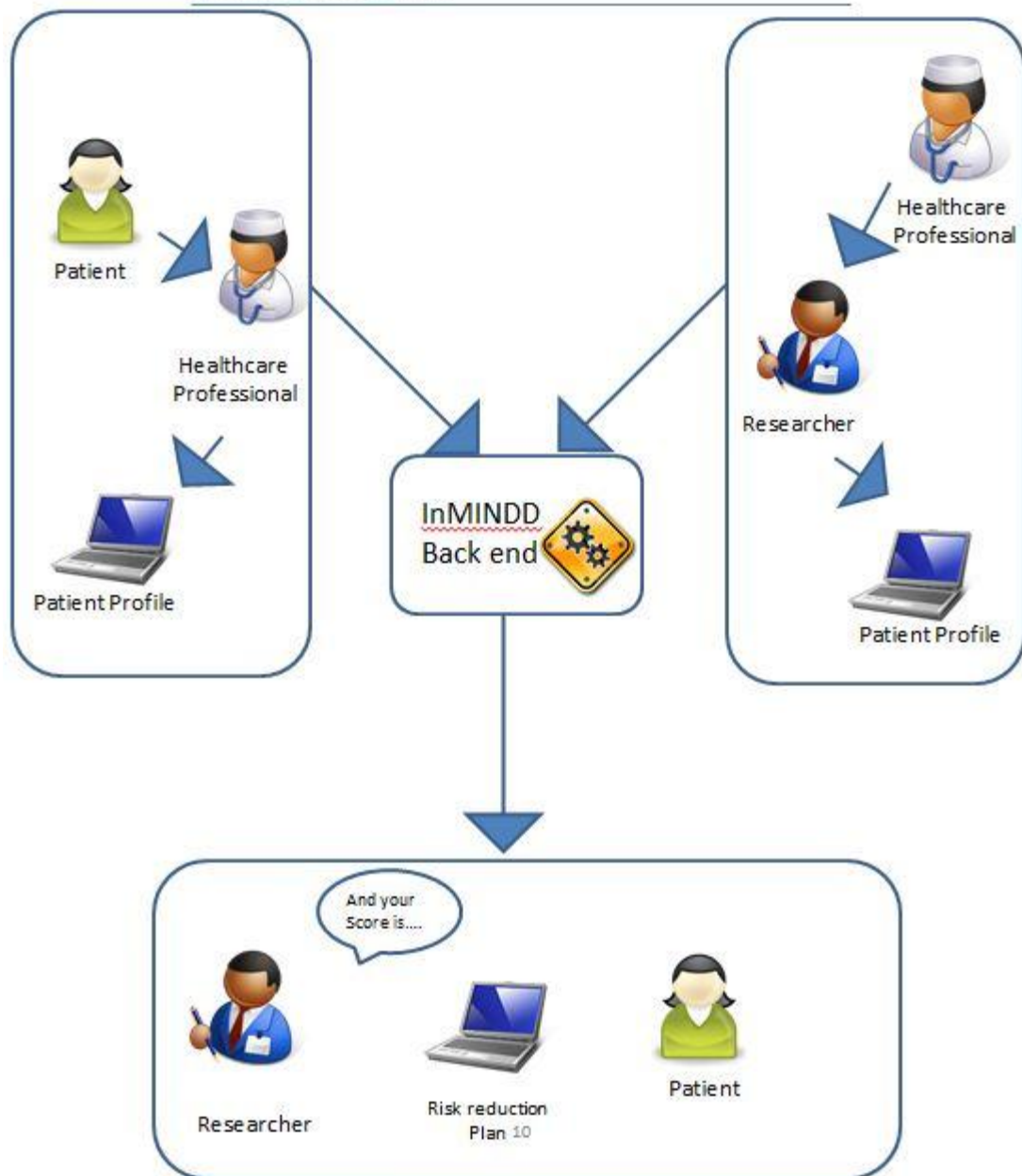
Figure 1 NMINDD Top Level care flow 1
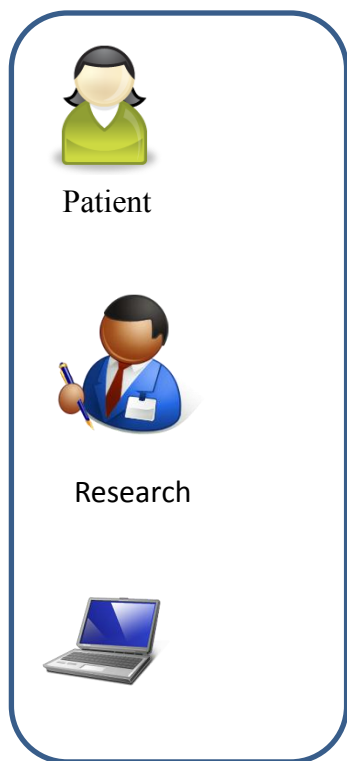
Figure 2

Initial Screening Process

The initial screening will determine eligibility for enrolment. Figure 2 illustrates the registration process with the aid of a use case diagram. The Researcher will administer the screening questionnaire, consent form (consent will need to comply with the soon to be published Health Information Bill Q1 (2015) and plain language statement to the patient.[1] This is a paper based process. Patients who meet the inclusion criteria, and agree to take part in the research will be asked to register with the In-MINDD intervention once they have had time to consider their participation[2].

Individual Health Identifiers and LDAP

For an overview of individual health identifiers see National Standard Demographic Dataset and Guidance for use in health and social care settings in Ireland (HIQA, 2013). The service user should be identified as role type: client. This process

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[1] If this is a paper based process or will it be completed on a mobile device and the consent will need to comply with the soon to be published Health Information Bill Q1 2014. December unique health identifier. Update inputs data defined as per health information bill 2014.

[2] Consider drilling down to different interventions. For example what does intervention one include in phase one; The client will be registered by administrator role on to the inmindd register, identified as role type client. Process will include username define data type and password ref as per Health Information Bill guidelines

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will include Lightweight Directory Access Protocol, (LDAP) username define data type and password reference as per Health Information Bill guidelines.

Registration process

The researcher will help register the client who will provide a personal username and password which the client will later use at home to access the INMINDD self- report portal online. The researcher will direct the client to the self-report patient portal and explain how to input and update information. Within the self-report service user portal fields will include inputs such as education, occupation, social interaction, hobbies/pastimes, physical activities, dietary information (for a detailed list see the Irish profiler inputs doc v2).
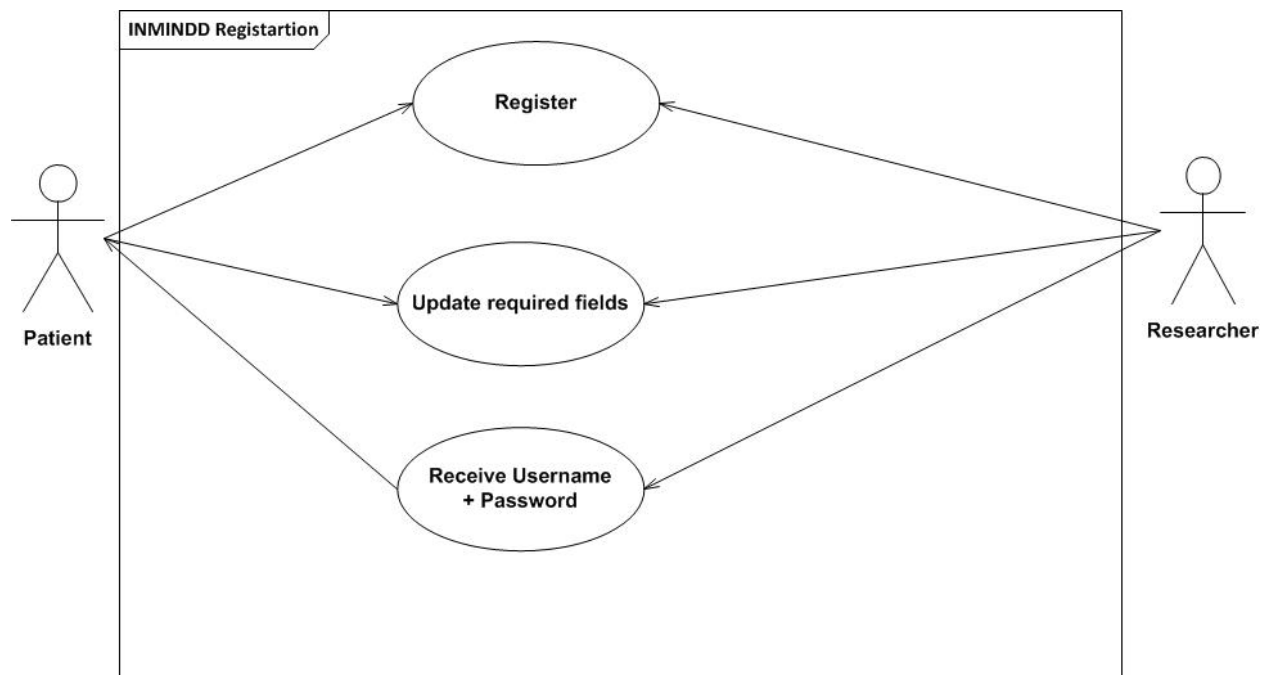
Figure 3

Fig 4: Data flow
Figure 4 represents a high level overview of the system.
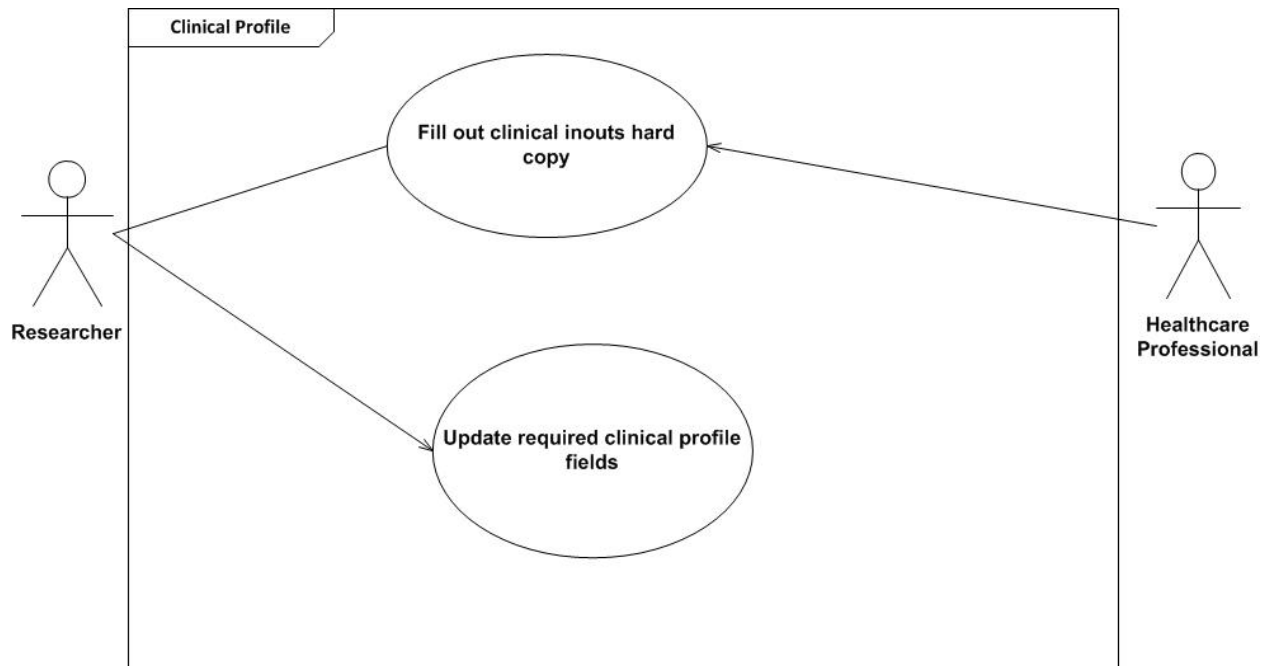
Fig 5: Registration Use case
Clinical profile registry

The researcher will enter clinical information (BMI, cholesterol, blood pressure) that has been made available on a hard copy by a member of the primary healthcare team (GP [3]). Figure 5 present the interaction between researcher and healthcare professional in a use case diagram.

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[3] Health data is considered sensitive data if the researcher is downloading this information from Socrates then permission will need to be sought and obtained. Frequency time intervals for access to this data either on Socrates or from the client also has to be considered. How many BMI measurements are taken over how long link this section to the data requirements piece you did last week in regard to data types and consider cardinality in terms of processes. My thinking on this is that there will be 0 to many data entries on this particular process each data entry requires a time stamp dd/mm/yyyy and is associated with administrator number. Who signs off that this data is correct in the inmind resource it has to be the researcher who is nominated as the administrator for the prototype I think.

Figure 6 on the following page presents a data flow diagram for the new user registration. Depending on the approach taken by INMINDD either the researcher or participant will enter this information. There will be interaction between the INMINDD researcher, service user and the clinician during registration. The researcher/service user will enter clinical information into the clinician portal that has been taken that has been made available on hard copy by the clinician. The following steps must be present in this process:

- Map IHI to INMINDD identifier

- Sign on to In-MINDD using admin password

- Generate new user on INMINDD registry

- System form is available to complete new user detail template form put in

- On date of birth field Call to check the date of birth query if date of birth between 1953 and 1968 if yes then other fields can be completed if no message service user outside parameters of inclusion criteria

- Review and sign off material correct on form

- Option to print

Figure 6 Clinical Registration Process
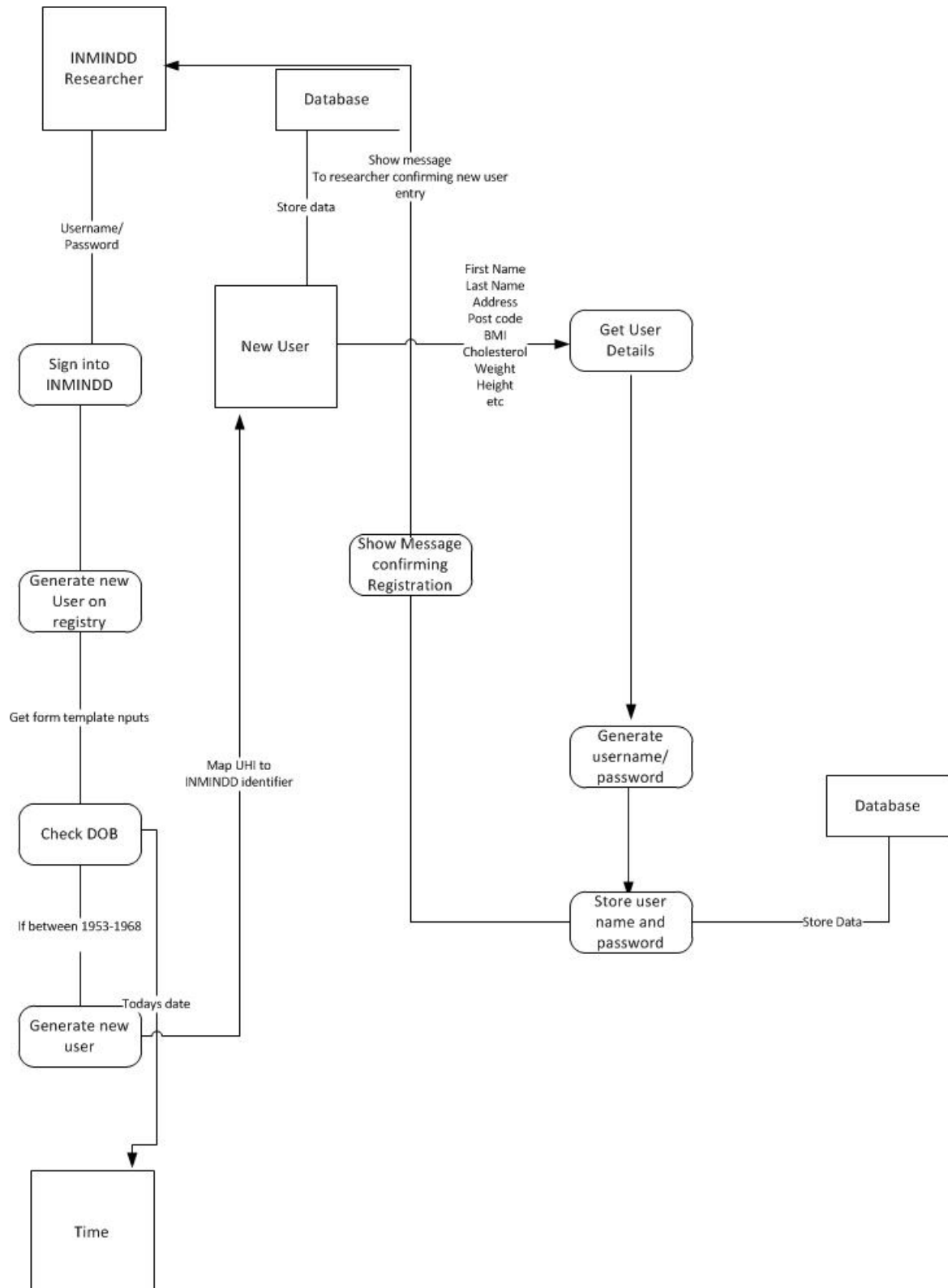
<u>Self-report Portal data flow diagram</u>

The user updates self-report information using the self-report portal. The user is required to enter a username and password. The user then is required to enter a number of mandatory. The system stores and updates these details. When complete the system will send a message to the clinician confirming registration of the client. INMINDD will then generate a dementia risk score and risk reduction strategy to be approved by the clinician. Before this part of the process is finalised, any outstanding ethical issues that arise need to be teased out and given great consideration so that the process closely follow ethical practices.

Figure 7
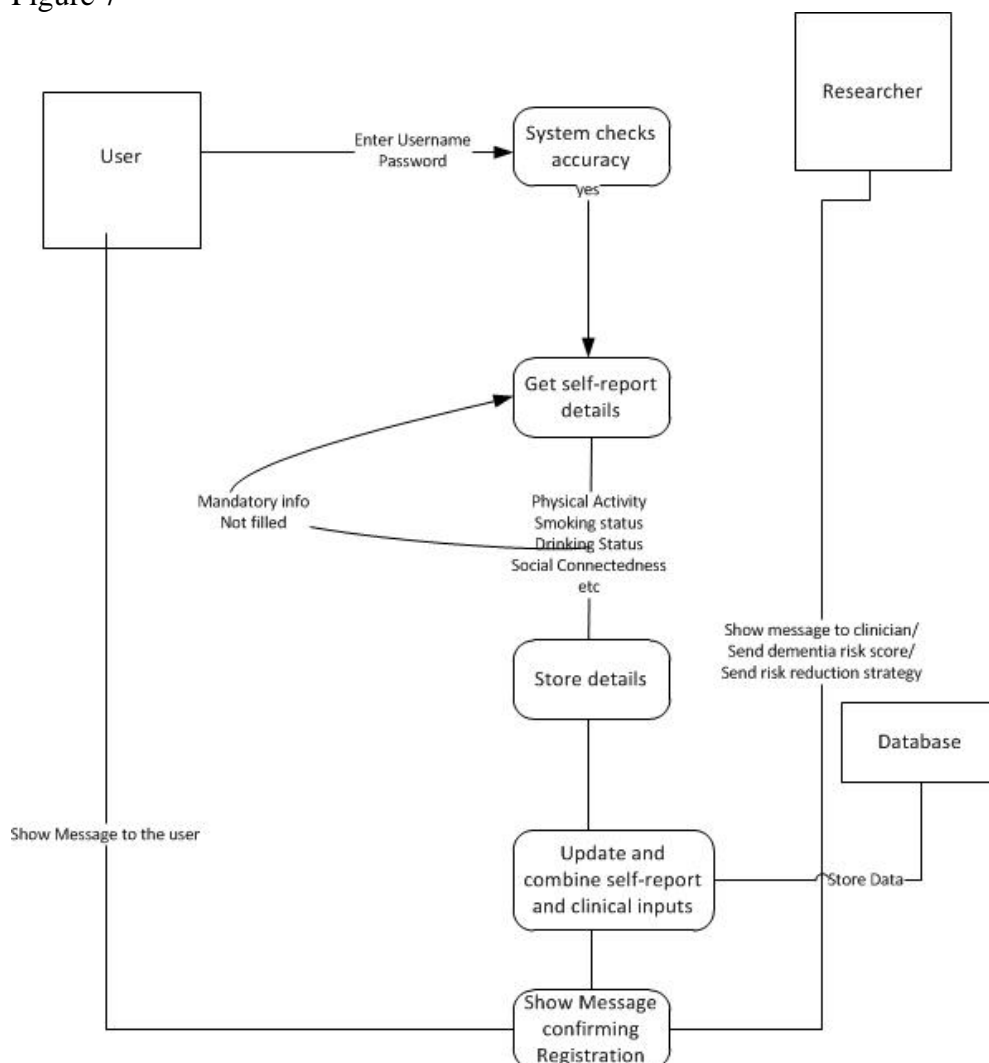
<u>Risk reduction strategy</u>

This stage of the process needs to be elucidated further. For the present it is proposed that following the approval of the risk reduction strategy by the clinician the user is contacted. A Risk reduction meeting is scheduled that is attended by the researcher and client. The clinician has approved the risk reduction strategy. The user logs into the service user portal and is presented with their In-MINDD score. The presentation of outputs here will be phrased as 'room for gain/improvement' instead of 'dementia risk'. The system will then prompt the user to view a dementia risk reduction program. The following steps must be present in this process:

- User receives email/phone call that new data is available their record has been updated then user accesses INMINDD using password and username
- Risk reduction strategy must have been approved by clinician and service user
- INMINDD system checks accuracy of password and username by checking LDAP registry to ensure user currently active on the INMINDD system if approved
- User then accesses dementia risk and reduction plan
- Opt to print or save the plan to alternative location

There are governance issues to be considered during this phase. These include questions such as who is responsible, who owns the data and who is accountable from a data controller perspective? What protocols are established for data updating of required field for example how often are the fields updated and are there some fields that are mandatory and some that are optional?
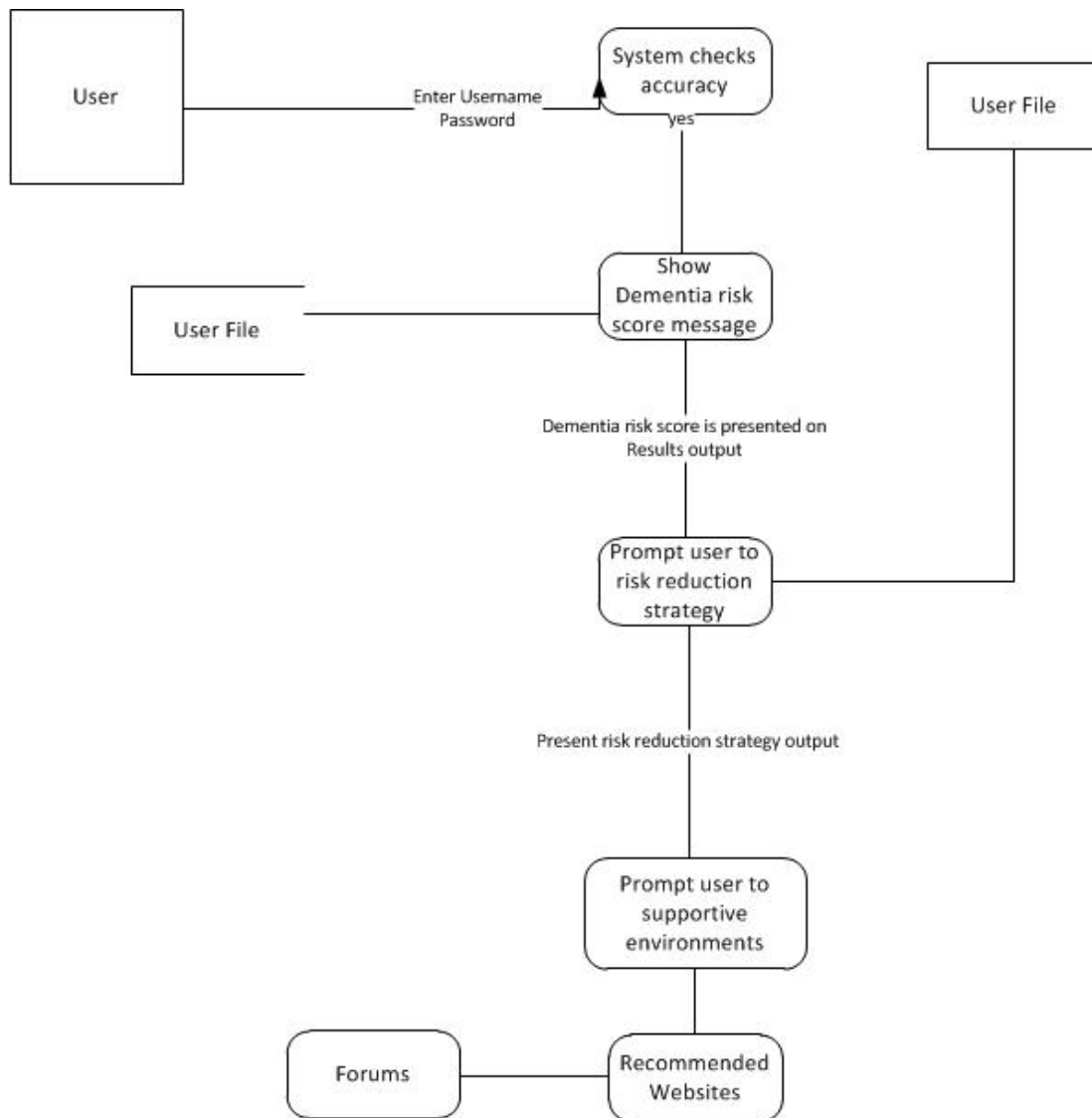
Figure 9
Validation Process

Reference List

Health Information and Quality Authority. (2013*). National Standard Demographic Dataset and Guidance for use in health and social care settings in Ireland.* Retrieved from http://www.hiqa.ie/publications/about-regulation-residential-services-children-and-adults-disabilities-guidebook-2013

Requirements Specification Document for the In-MINDD tool

Functional and Non –Functional Requirements

Author: Kevin Power

Version	Description of Change	Author	Date
Version 1.0		K.Power	13/07/2015

Stakeholder Name	Role
Service User	End User
In-MINDD Team	Developers
In-MINDD Team	Client
GP	Client

1.0 Executive Summary

The requirements specification document is to serve as the mandate for the design, development and realisation of the technical component of the In-MINDD tool within the In-MINDD Project.

1.1 INTRODUCTION

The In-MINDD tool can be descibed as a personal health record for early screening of dementia risk factors which produces a service user centred plan which may help to reduce future risk of dementia.

1.2 System Description

The In-MINDD tool is a web based program that contains two sections a profiler and support environment. The on-line profiler collects personalised demographic, lifestyle and clinical information on users aged 40-60 years. This results in individuals receiving information in the form of a personalised Lifestyle for Brain Health (LIBRA) score and profile. An on-line support environment gives individuals information on their identified risk factors, outlines the national evidence based partactice guidelines in their relevant country and supports goal setting to change behaviour see Figure 1 (p. 3). Service users are identified by their GP in each of the partner countries Ireland, Scotland, France and The Netherlands.

Audience

This document is intended to be read by all responsible for the development of the In-MINDD tool including IT developers and the In-MINDD partners in all partner countries.

Purpose and Scope of this Specification

This document is the definitive specification of the user requirements for the In-MINDD tool to be developed by the In-MINDD project partners. It is a primary input to the technical development of the In-MINDD tool.

The system name is the In-MINDD Tool. The In-MINDD tool was built to capture data on dementia related Risk Factors (RFs); contain sufficient knowledge about these concepts to allow a computer system to understand them; and finally to allow a computer system to calculate a score based on their state i.e. the measures for a specific RF. It contains logic that draws relationships between the RFs and associates each RF with one or more questions in the Question Database. In this way the system created links from RFs to specific questions and in turn to actual data (answers) thus, building knowledge about RFs from facts.

1.4 In-MINDD tool behaviour model data flow diagram

The following high level behaviour model indicates the dynamic behaviour of the system. This indicates what happens when the system responds to the registration of a new service user.
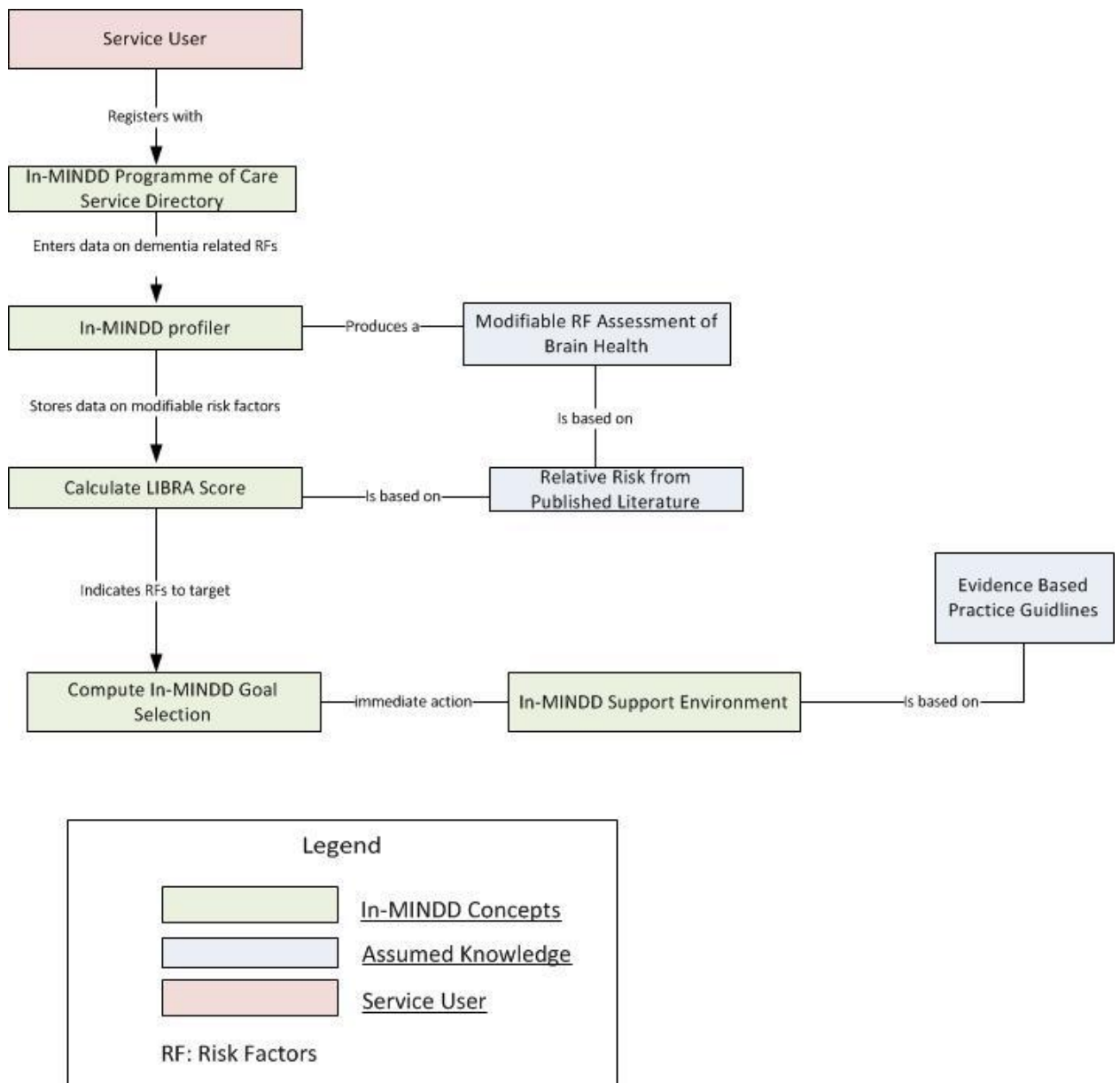
Figure 4: In-MINDD Tool Data Flow Diagram

Functional and non-functional requirements elicited for the In-MINDD tool. Functional Requirements elicited for the In-MINDD tool. Functional requirements are presented form the perspective of concepts and data types. Full details of the available from the In-MINDD website: http://inmindd-profiler.appspot.com/InminddProfiler.html .

Out of Scope

Requirements unrelated to the In-MINDD tool.

System Concepts

The In-MINDD profiler consists of an online questionnaire. The data collected via the In-MINDD profiler includes the following:

• Demographic information about participants (including age, sex, country of birth, marital status, employment status, educational attainment (localized to each country), level of occupational attainment, and living arrangements)
• Information about the participant's health including height and weight (to calculate BMI). This requires inputting some clinical data (blood pressure and cholesterol level), which will be provided, if available (i.e. relevant tests have been conducted and in the required timeframe) to the individuals by their GP in advance.
• Information about family medical history (i.e. dementia, cardiovascular disease and diabetes mellitus)
• Information about alcohol consumption and current and past smoking habits

LIBRA Score

Using the relative risks from the identified literature, the In-MINDD team developed a risk score algorithm in which the relative risk of each factor was standardised and weighted to a reference value (lowest relative risk), in this case the relative risk for low/moderate alcohol consumption. The final model, based on the 12 risk factors shown in Table 1, is then used to produce the personalised Lifestyle for Brain Health (LIBRA) global score and profile for individuals participating in the feasibility trial. Coronary heart disease, Chronic Kidney disease and diabetes are non-modifiable risk factors highlighted in red. A total modifiable risk score is given informing participants of the risk factors that they need to work to reduce. A total manageable risk score is given for non-modifiable risk factors. For risk factors the participant does not need to reduce a message is given No Risk Keep it up! For similar calculation of dementia risk see Kivipelto et al. The Lancet Neurology. 2006;5(9):735-41

Table 1: Modifiable risk and Protective factors identified by In-MINDD as potentially increasing or reducing dementia risk

RISK/PROTECTIVE FACTOR	Risk Factor	Protective Factor	WEIGHT	max. 'gain'	%max. 'gain'
Alcohol	0.74	-0.30	-1.0	1	5.3
Physical inactivity	1.39	0.33	+1.1	1.1	5.9
Coron. heart dis.	1.38	0.32	+1.1	1.1	5.9
Chron. kidney disease	1.39	0.33	+1.1	1.1	5.9
Diabetes	1.47	0.39	+1.3	1.3	7.0
Cholesterol	1.54	0.43	+1.4	1.4	7.5
Smoking	1.59	0.46	+1.5	1.5	8.0
Midlife obesity	1.60	0.47	+1.6	1.6	8.6
Midlife hypertension	1.61	0.48	+1.6	1.6	8.6
Healthy diet	0.60	-0.51	-1.7	1.7	9.1
Depressed mood	1.85	0.62	+2.1	2.1	11.2
High cognitive activity	0.38	-0.97	-3.2	3.2	17.1
				18.7	100.0

1.6 Applicable Reference Documents

The In-MINDD profiler also collects data on participants' mood, physical activity, cognitive activity and diet via four validated instruments, which have been carefully selected and adapted where necessary. The four instruments are:

- The mood section is based on a self-report depression scale called the (1) Center for Epidemiologic Studies Depression Scale CES-D (Radloff, 1977).
- Physical activity is based on a self-report measure of physical activity the European Prospective Investigation into Cancer and Nutrition (EPIC) Physical Activity Questionnaire (Wareham et al., 2003).
- Cognitive Activity – Cognitive Reserve Index questionnaire CRIq (Nucci et al., 2012) - adapted (with permission) for self-administration and online use
- The Diet section is based on adapted version of the Mediterranean Diet Adherence Screener (MEDAS) (Martınez-Gonzalez et al., 2012)
- The In-MINDD Document of Work (DOW). The system must comply with the In-MINDD DOW

Background

The In-MINDD tool is based on a dementia risk model, which was developed following a systematic literature review and Delphi consensus study which identified the following as the most significant modifiable risk/protective factors for developing dementia (i.e. low cognitive activity, healthy/Mediterranean diet, low/moderate alcohol consumption, coronary heart disease, physical inactivity, chronic kidney disease, diabetes, cholesterol, smoking, obesity in midlife, hypertension in midlife, depression,).

Dublin City University (DCU) was responsible for the IT Development and co-design of the In-MINDD Online Profiler and Support Environment. This functional requiremets document was produced by DCU in order to document the functional and user requirements for the In-MINDD tool.

Assumptions and Constraints

Assumptions

The In-MINDD tool is a web based program available to any users with access to the internet. All service users will need to have some access to the Internet for registration and to access the profiler.

Constraints

In-MINDD Data Constraints

Profiler data is collected in each country by accessing a dedicated In-MINDD password protected website. Data is anonymized, with participants each allocated a unique study number. Data is collected has been held securely through a Google App Engine cloud web application (security is a key component of each of Google's cloud computing elements, including Google App and other cloud web applications, for example, Google's approach to IT security and the level of security guaranteed for the Google App engine are outlined a Google White Paper, which is available at the following link: https://cloud.google.com/files/GoogleCommonSecurityWhitePaperv1.4.pdf)

Ethical/Legal Requirements

At the end of the study, anonymised data from the In-MINDD system is transferred securely to the Robertson Centre for Biostatistics (RCB) in the University of Glasgow for analysis. The Centre sits in the Glasgow Clinical Trials Unit (GCTU), a United Kingdom Clinical Research Collaboration fully registered CTU. The source data was stored on the RCB secure filestore and uploaded to the study database. Both the file store and the study database are backed up daily.

Tapes were stored in a fire-proof safe every two days and stored off-site every seven days. All data handled by the RCB was anonymised and access restricted to study personnel. The RCB manages all studies in accordance with its internal standard operating procedures and all relevant legal and regulatory guidelines. It has extensive experience of managing data in the context of UK and EU privacy and data protection legislation. The RCB is certified for ISO 9001:2008 for its quality systems, has TickIT accreditation for its software development and is BS7799 compliant.

Delivery Date

The delivery date for the In-MINDD tool is October 2014.

2 Methodology

Information gathering methods are described in chapters 6, 7 and 8 of the thesis.

3 Functional Requirements

Functional and user requirements were elicited from November 2012 to October of 2104. The first service user was registered with the live system in October 2014. Table 2 indicates the functional requirements for the In-MINDD profiler.

Table 2: In-MINDD tool Data Types

Table Name	Column Name	Data Type	Primary Key (PK)	Not Null (NN)	Unique Constraint (UC)
Demographic Information	Patient ID	Varchar	✓	✓	
	Timestamp	TimeStamp	✓	✓	✓
	Age	Int			
	Sex	Varchar			
	Country of Birth	Varchar			
	Marital Status	Varchar			
	Employment status	Varchar			
	educational attainment (localized to each country)	Varchar			
	level of occupational attainment	Varchar			
	living arrangements	Varchar			
Medical Information	Patient ID	Varchar	✓	✓	
	Timestamp	TimeStamp	✓	✓	
	Height in Centimetres	Double			
	Feet	Double			
	Inches	Double			
	Weight in Kgs	Double			
	Stone	Double			
	Pounds	Double			
	Total Cholesterol in MMol	Double			
	Cholesterol (been told that one has)	Varchar			
	High Total Cholesterol	Varchar			
	lifestyle for cholesterol (take Medication for)	Varchar			
	Medication for Cholesterol	Varchar			
	Cardiovascular Disease	Varchar			
	High Blood Pressure (Been told that one has)	Varchar			
	Blood Pressure (What is)	Varchar			
	Systolic Blood Pressure	Varchar			
	Diastolic Blood Pressure	Varchar			
	Blood Pressure Medication	Varchar			
	Diabetes Mellitus (been told that one has)	Varchar			
	Diabetes Mellitus (receiving treatment for	Varchar			
	High Sugar levels in Urine	Varchar			
	Chronic Kidney Disease	Varchar			
Family Medical History	Patient ID	Varchar	✓	✓	
	Timestamp	TimeStamp	✓	✓	
	Mother_Dementia	Varchar			
	Mother_CVD	Varchar			
	Mother_Diabetes	Varchar			

	Father_Dementia	Varchar			
	Father_CVD	Varchar			
	Father_Diabetes	Varchar			
	Sibling_Dementia	Varchar			
	Sibling_CVD	Varchar			
	Sibling_Diabetes	Varchar			
Smoking & Alcohol Consumption	Patient ID	Varchar	✓	✓	
	Timestamp	TimeStamp	✓	✓	
	Smoker_type	Varchar			
	Current_year_start	INT			
	current_num_smoke per day	INT			
	Former_Year_start	INT			
	Drinks_Frequency	Varchar			
	Num_Frequency	Varchar			
About your Feelings	Patient ID	Varchar	✓	✓	
	Timestamp	TimeStamp	✓	✓	
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
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	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	CES-D 1	Varchar			
	Depression	Varchar			
	Treated	Varchar			
Physical Activities	Patient ID	Varchar	✓	✓	
	Timestamp	TimeStamp	✓	✓	
	DIY_Hours	Double			
	Summer_walking_Hours	Double			
	Winter_walking_hours	Double			
	Summer_Cycling_Hours	Double			
	Winter_cyclting_hours	Double			
	Summer_Garden_hours	Double			
	Winter_Garden_hours	Double			
	Summer_physical_Hours	Double			
	Winter_physical_hours	Double			

	summer_housework_hours	Double			
	winter_housework_hours	Double			
	flight_stairs	Double			
	vigorous_hours	Double			
	physical_activity_work	Varchar			
	vigorous	Varchar			
Cognitive Activities 1	Patient ID	Varchar	✓	✓	
	Timestamp	TimeStamp	✓	✓	
	formal_education_years	Double			
	nonformal_education_years	Double			
	manager	INT			
	manager_simul_years	INT			
	professional	INT			
	professional_simul_years	INT			
	technician	INT			
	technician_simul_years	INT			
	clerical	INT			
	clerical_simul_years	INT			
	service	INT			
	service_simul_years	INT			
	agriculture	INT			
	agriculture_simul_years	INT			
	craft	INT			
	craft_simul_years	INT			
	plant	INT			
	plant_simul_years	INT			
	elementary	INT			
	elementary_simul_years	INT			
Cognitive Activities Two	Patient ID	Varchar	✓	✓	
	Timestamp	TimeStamp	✓	✓	
	household_years	INT			
	driving_years	INT			
	leisure_years	INT			
	technology_years	INT			
	social_years	INT			
	cinema_years	INT			
	gardening_years	INT			
	volunteering_years	INT			
	artistic_years	INT			
	exhibitions_years	INT			
	holidays_years	INT			
	books_years	INT			
	number_children	INT			
	pets_years	INT			
	bank_account_years	INT			
	reading	Varchar			
	household	Varchar			
	driving	Varchar			
	leisure	Varchar			
	technology	Varchar			

	social	Varchar			
	cinema	Varchar			
	gardening	Varchar			
	children	Varchar			
	volunteering	Varchar			
	artistic	Varchar			
	exhibitions	Varchar			
	holidays	Varchar			
	books	Varchar			
	raised_children	Varchar			
	pets	Varchar			
	bank-account	Varchar			
Diet	Patient ID	Varchar	✓	✓	
	Timestamp	TimeStamp	✓	✓	
	Culinary-fat	INT			
	oil_consume	INT			
	vegetable_servings	INT			
	fruit_units	INT			
	red_meat	INT			
	butter	INT			
	carbonated_beverages	INT			
	wine_week	INT			
	legumes_week	INT			
	fish_week	INT			
	sweets_week	INT			
	nuts_week	INT			
	prefer_chicken	INT			
	sauce_week	INT			
LIBRA Score	UserID	Varchar	✓	✓	
	time-score	Timestamp	✓	✓	
	gender	Varchar			
	alchol	Float			
	chol_Netherlands	Float			
	chol_others	Float			
	chronic_kidney_disease	Float			
	depression	Float			
	coronary_heart_disease	Float			
	diabetes	Float			
	healthy_diet	Float			
	High_cognitive_activity	Float			
	midlife_hypertension	Float			
	midlife_obesity	Float			
	physical_inactivty	Float			
	smoking	Float			
Goals	id_goal	INT	✓	✓	
	id_user	Varchar	✓	✓	
	timestamp	Timestamp	✓	✓	
	Comment	Text			
Ask the Experts	id	INT	✓	✓	

	language	Varchar	✓	✓	
	country	Varchar		✓	
	image_url	Text		✓	
	description	Text		✓	
FAQ	id	INT	✓	✓	
	language	Varchar	✓	✓	
	Question	Text		✓	
	answer	Text		✓	
Useful Apps	id	INT	✓	✓	
	language	Varchar	✓	✓	
	name	Varchar		✓	
	logo_url	Varchar		✓	
	category	Varchar		✓	
	description	TEXT		✓	
Support Risk Factors	id	INT	✓	✓	
	language	Varchar	✓	✓	
	name	Varchar			
	image_url	Varchar			
	desc_keep	TEXT			
	desc_improv	TEXT			
	sources	TEXT			

3.2 In-MINDD Reference Document Calculations

This section provides information on the reference documents used to calculate; depression, physical activity or inactivity, cognitive inactivity and a healthy or unhealthy diet. Table 3 presents the reference documents in terms of inputs, process and outputs.

Table 3: In-MINDD tool Reference Documents

<table>
<tr><td colspan="4" align="center">In-MINDD Tool Reference Documents</td></tr>
<tr><td>Instruments</td><td>Inputs</td><td>Process</td><td>Outputs</td></tr>
<tr>
<td>CES-D (<i>Depression</i>)

About Your Feelings</td>
<td>CES-D questions 1-20.

Datatype: Varchar</td>
<td>
The total CES-D score is calculated as a sum of responses to 20 questions. The range of possible scores is between 0 (for those who say 'rarely or none of the time' to all 20 questions and 60 (for those who say 'most or all of the time' for all 20 questions).

Respondents are given a set of 20 statements and asked to indicate how frequently over the past week they felt this way using a four-point Likert scale, i.e.

<table>
<tr><td>Scoring Item Weights</td><td>Rarely or none of the time (less than 1 day)</td><td>Some of a little of the time (1-2 days)</td><td>Occasionally or a moderate amount of the time (3-4 days)</td><td>All of the time (5-7 days)</td></tr>
<tr><td>Items 4, 8, 12, 16</td><td>3</td><td>2</td><td>1</td><td>0</td></tr>
<tr><td>All other items</td><td>0</td><td>1</td><td>2</td><td>3</td></tr>
</table>
</td>
<td>A CES-D cut-off score of 16+ is indicative of 'mild' or 'significant' depressive symptomatology.

Participants who score less than 16 will be told that low mood is not a problem for them right now. Those whose score is 16 or above and indicative of 'mild' depressive symptomology will be told that their answers suggest that low mood may be a problem for them.</td>
</tr>
<tr>
<td>EPIC physical activity questionnaire</td>
<td>Answers to EPIC Physical Activities section</td>
<td>
<table>
<tr><td></td><td colspan="4" align="center">Occupation</td></tr>
<tr><td>Cycling/physical exercise (h/week^{-1})</td><td>Sedentary</td><td>Standing</td><td>Physical</td><td>Heavy manual</td></tr>
<tr><td>0</td><td>Inactive</td><td>Moderately Inactive</td><td>Moderately Active</td><td>Active</td></tr>
<tr><td>0-3.5</td><td>Moderately Inactive</td><td>Moderately Active</td><td>Active</td><td>Active</td></tr>
<tr><td>3.5-7</td><td>Moderately active</td><td>Active</td><td>Active</td><td>Active</td></tr>
<tr><td>>7</td><td>Active</td><td>Active</td><td>Active</td><td>Active</td></tr>
</table>
</td>
<td>Those who are assessed as have having low physical activity will be given a personalized plan with tips on how to get physically active and will have access to supports to enable them to do this.</td>
</tr>
</table>

| Cognitive Reserve Index Questionnaire (CRIq) Nucci et al. (2012) | Answers to CRIQ. Cognitive Activities Section 1 & 2 | CRIq sub scores (CRI-Education, CRI-Working Time Activity and CRI-Leisure) are calculated and from this a total CRIq score is calculated based on an algorithm. Five possible outcomes are possible based on the following cut-off values: Low = ≤70; Medium/Low = 71-85; Medium = 86-115; Medium high = 116-130; High = >130. | Participants who score 100 or more on the CRIq will be told that that they are cognitively active and will be encouraged to continue participating in these activities. Participants who score less than 100 will be told that their cognitive activity is low but that there is room for improvement and why staying cognitively active is important. The participants will be given a personalised plan which will include information on strategies that they can be adopted to improve their cognitive reserve such as joining the local library or joining or staring a book club with friends, becoming a volunteer, taking an evening class and of the importance of sustaining activities such as these through mid-life and into later life. Their GP will receive the same information as the participant and participants will be free to discuss this with their GP if they so wish. Participants with a score of 100 or more will be informed of the benefits of being cognitively active and encouraged to make improvements in this area and be directed to ways in which they can do this. |
| Mediterranean Diet Adherence Screener – | Answers to MEDAS | Either 0 or 1 point is added to the score for each item, according to a respondent's answer. Total score ranges between 0 and 14 with a score of 10 or less indicative of a weak adherence to a Mediterranean diet, whilst the | Participants with a high adherence to the Mediterranean diet will be informed that they have scored well and |

MEDAS (Martınez-Gonzalez et al., 2012).	provided in Diet Section	opposite is the case for a score of 11-14.	encouraged to continue with this diet and given the reasons why, i.e. its roles in helping to prevent heart disease, stroke and dementia. Participants with a weak adherence to the Mediterranean diet will be told that their score is lower than average and will be informed of ways in which the Mediterranean diet can be used to lower risk of heart disease, stroke and dementia and will be encouraged to increase their consumption of olive oil, nuts, beans, fish, fruits and vegetables.

4 User Requirements (UR)

The following user requirements dictate a number of aspects of the In-MINDD tool.

Look and Feel Requirements

UR1 The website shall appear to be EU FP7 funded.

UR2 Messages should be high light the positive

UR3 The most important information should be given first

UR4 Clearly state the actions users can take

UR5 Tell the user what is to gain by following the messages

UR6 Use images to help tell the story.

UR7 Name sections such as A1, A2, A3 to help situate users

UR8 Provide feedback (such as a bar or a percentage meter to provide feedback)

UR9 Shall provide a save and return function

Usability Requirements

UR10 The website shall be easy to use by a member of the public without training with the aid of a researcher if needed.

Performance Requirements

UR11 The website shall randomise a participant to experimental or control group following registration and produce a confirmation message.

Maintainability Requirements

UR12 The website shall be translated into 3 different languages English, French and Dutch.

Security Requirements

Confidentiality

UR13 The product shall ensure that the name of participants and their data can be accessed only by authorized users.

UR14 The program shall distinguish between authorized and non-authorized users.

UR15 Each participant shall be assigned a Unique Identifier Code (UIC).

UR16 The UIC appears in the database but the password that the participant creates shall be encrypted immediately after it is entered on the registration page and remains encrypted in the database.

UR17 No personal information (e.g. name, address, date of birth etc.) shall be stored in the database.

UR18 The participant shall have the option of entering an email address.

UR19 The email address shall be encrypted immediately after it is entered on the registration page.

UR20 The email address shall be stored in a completely separate part of the database than the part that stores the responses to the questions on the screen.

UR21 The part of the database that stores the participant responses shall have no interaction with the part of the database that stores the encrypted email addresses.

Standards

UR22 The encryption method for the password and email address shall create a hash for these fields using the sha1 (secure hash algorithm) outlined by DesAutels (1997).

> UR23 Map patient id to the HIQA Individual Health Identifier (IHI). At the time of writing standards for the IHI were not available for the In-MINDD tool development. Standards are now available on the HOQA website: http://www.hiqa.ie/publications/information-governance-and-management-standards-health-identifiers-operator-ireland

5 References

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Nucci, M., Mapelli, D. and Mondini, S. (2012) 'Cognitive Reserve Index questionnaire (CRIq): a new instrument for measuring cognitive reserve, *Aging, Clinical and Experimental Research,* 24(3): 218-26.

Radloff, L.S. (1977) 'The CES-D scale: a self-report depression scale for research in the general population', *Applied Psychological Measurement,* 1: 385-401.

Appendix L: <u>Issue Questions in Chronological order</u>

Early Jan 2013

1. What are the main primary care practice management software providers in Ireland?
2. What will the GP want from a new system that detects risk and protective indicators for dementia in later life?
3. What similar products are currently out on the market?
4. Who are the main players in the eHealth arena in Ireland with regard to primary care?
5. What are the main practice management software providers in Ireland?
6. Should In-MINDD embed into the local practice management software or be provided separately?

Late Jan 2013

7. What are the main primary care practice management software providers in Ireland?
8. How do we approach primary care practice management software providers with a view to collaboration?
9. What types of data that are collected by GPs on service users?

June 2013

10. Should In-MINDD be embedded into the local practice management software or be provided separately?
11. What service user information is collected in general practice?
12. How is information stored?
13. How do GPs prefer to contact service users?
14. How would one create a custom investigation for the In-MINDD lifestyle for brain health risk and protective factors?

15. Who will input service user data into the IN-MINDD program GP, service user or researcher?
16. What supports should be offered to the end user?
17. What do GPs know about the modifiable risk factors for dementia?

Appendix M: <u>User Recommendations in Chronological Order</u>

Early Jan 2013

- Reduce the cognitive load on the GP

- GP should not have to enter data twice

- Benefits realization should be stressed.

- GP need to understand the direct tactical benefits of the In-MINDD tool to their own work

- Producing a tool that will embed into a particular GP practice management software system will lead to reduced uptake among GPs. Certain practice management software providers are more open to collaboration than others.

- Stakeholders must understand the value and demand for In-MINDD to improve chances of engagement.

Late Jan 2013

- The research team needs to collaborate with one of the Irish practice management software companies in order to review the types of service user information that are collected by GPs.

- Stakeholders need to understand that there is a demand for the In-MINDD program from service users.

June 2013

- The tool should be offered as a stand-alone web based program that does not require any practice management software host system to run.

- Need to understand what clinical data are currently collected by individual GPs. Clinical information includes blood pressure, Body Mass Index (BMI), cholesterol, kidney function, mood information, mental health information, smoking/alcohol status, diet, exercise, family medical/mental health history, educational, occupation.

- GP practice management systems are not encouraged to use cloud storage due to data protection issues).

- The program must not provide the GP with additional data entry work.

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- GPs are encouraged not to use cloud storage.

September 2013

- The In-MINDD tool should minimize GP role in data entry. Where possible data entry should be done by the individual using the In-MINDD tool.
- The tool should be web based
- The In-MINDD tool should not create undue support work for the GP. The support environment should be comprehensive and easy to use minimising need for GP visits following use of In-MINDD to discuss risk factor supports with GP.
- The In-MINDD tool should mirror other risk assessment tools such as the Framingham cardiovascular risk calculator.
- The In-MINDD tool should have the functionality to be part of an overall health profile that gives a risk profile breakdown not only for dementia but cardiovascular disease, cancer stroke, chronic kidney disease. However in order to create a tool like this it is first necessary to create algorithms that can predict each disease in this case In-MINDD can predict risk of dementia in later life.
- Service users should have more personal involvement and control of their personal healthcare.
- In-MINDD should facilitate the awareness raising of modifiable risk factors for dementia.
- In-MINDD should help to make dementia less taboo or reduce stigma around the topic of dementia.

Appendix N: <u>Service User Email sent one month after registration.</u>

Dear In-MINDD Participant,

By now we hope you will be familiar with the many features of the Support Environment.

'Your Goals' section: We designed this section of the In-MINDD support environment as a way of supporting you to make lifestyle changes that will help you protect your overall brain health.

If you have chosen one or more goals from any of the factors that you find under your 'Room for improvement ', we hope that by now you have begun to incorporate some changes into your lifestyle.

Incorporating goals into your everyday lifestyle can be challenging, improvements can be slow but even very small changes are a positive step towards a healthy brain lifestyle. If you find the goals we have set out are not suited to you, you can opt to create your own goals that would better fit your particular situation.

Remember if you have any factors that can be managed through healthier lifestyle choices please revisit your LIBRA profile and score.

Do let us know what works or what doesn't work for you. Even if you are finding it difficult to make lifestyle changes, we hope that you can have some fun along the way.

Kind regards,

The In-MINDD Team

If you have any questions or comments please contact:

Maria Pierce: 01 7006084 or email: maria.pierce@dcu.ie

Muriel Redmond: 01 7008034 or email: Muriel.redmond@dcu.ie

GP 1 Interview Notes

GP	Location	Time start	Time Finish	Present
GP1	DCU	2.00pm	2.52	Maria Pierce
				Kevin Power
				GP1

Transcribed Notes

Introductions

Maria and Kevin brief GP1 on InMINDD. GP1 is happy that he understands the project. GP1 has read the information sheet and consent form and signs the consent form.

Interview begins

Approx 2.10pm

Topic 1: General Knowledge of, attitudes to and current practice regarding dementia deterrence

KP: We have a topic schedule that is all based around what we have from In-MINDD at the moment. How are system looks. Then there is a bit about your attitudes towards what we are trying to do with dementia deterrence and risk analysis. Topic one is your General Knowledge of, attitudes to and current practice regarding dementia deterrence

GP:

We don't really try and deter dementia itself what we really do is target the risk factors more for stroke and heart disease. But obviously the way I'd see it as patients who you can probably motivate better for heart attack and stroke are probably patients who are interested in things and might actually be less likely to get dementia anyway because of just keeping more in tune and involved with everything that is going on around them. We do mini mental state examinations in a lot of elderly people because most of our older patients still drive well into their seventies and eighties so we do the mini mental state examination on them. But that is actually looking for something once it has occurred than actually looking for it before it has become obvious.

KP: Which software system do you use?

GP: We use HEALTHone (helix) which has a built in MMSE module on it.

KP: IS that Framingham health for cardiovascular?

GP: No Qrisk2 for calculating someone's risk of heart attack or stroke in the next ten years. Which is why I think this is really interesting because people are really interested in knowing their heart age. I'm sure people may be just as interested in knowing their brain age they'd find that quite interesting.

MP: So you would be familiar with the risk factors yourself for dementia?

GP: Well there is the stuff you can't do much about like genetic. If there is a history of young dementia in the family than its just trying to spot it and make sure the stuff is set up legally to deal with it in the future so they don't run into problems. Vascular dementia is a huge problem, if you can prevent the little mini strokes can be massively of benefit. Patient's understand their heart being protected more so than their brain being protected.

MP: I suppose it's the modifiable risk factors that we are looking at so it's the things you can do something about which is good.

KP. Would you offer specific advice about preventing dementia in the future or would you get many questions about that?

GP:

Sometimes you get questions from the worried well who may have forgotten some things. People who ask are usually the proactive healthy people looking to protect their health. You wonder if you are getting a self-selected population coming forward to prevent dementia who are generally the clean living healthy people interested their own health, current affairs palying bridge and that kind of thing.

MP: So they are the least likely to be at risk of dementia in the first place.

GP: exactly unless they were just unlucky genetics

Topic 2: In-MINDD

MP: So we talked about the eligibility criteria for people so I suppose one of the topics is looking at the Identification and recruitment of potential patients?

GP: We use standard coding procedures for all our diagnoses in work so we have lists of people with hypertension, high blood pressure, renal disease, hypercalcaemia, cardiovascular disease etc. It would be no problem recruiting people with one or multiple illnesses.

MP. What about data that would not usually be collected by a GP would you be aware of how cognitively or physically active a patient is?

GP: Generally if someone was to give me a name I'd probably be able to say that without much of a problem. The study group is between 40 and 60 is that correct.

MP: Yes

GP: Probably not so much we all know the sharp elderly. I would say I probably wouldn't have much of their cognitive skills that age when they are not sticking out as a really healthy 80 year old.

MP: one of the things we are thinking is that if someone is suffering from depression they might be less likely to be physically active or less likely to be involved in leisure activities so in a way we might catch them that way but that is something we will find out as we go on.

KP. In relation to recruiting patients. How do you contact patients or how do patients like to be contacted?

GP: We ring the patients. Patients are always happy/ interested to get involved. Patients never say no. If they are not working at the time they quite like that you thought about them and that you remember them. If you say you are doing something to help prevent dementia I'm sure a lot of them would be interested in taking part.

MP: Would the best thing to do is to prepare a standard letter that you could tailor make for your patients

GP: Yes we can print the letter on our own headed paper and post it out ourselves.

KP: Would we steer clear of email and text messages.

GP: We are generally told not to text or email patients because it's all data that wouldn't be secure. SO it's either fax, letter or a phone call from the data protection commissioner.

MP: You mentioned depression?

GP: We know depression is definitely linked to dementia and how much the depression itself causes the whole constellation of other risk factors that go along with it too such as alcohol smoking and other things. Sometimes we are reluctant to stick depression on patient's medical history as it can label them. It should be a problem to get someone in that age group. But in our heads we know who we are thinking about I can think of a few people already.

MP: Would you be worried about a depressive patients getting a high risk score. Talking about people with mild depression. Would this cause any anxiety or worry? Or could it be a positive thing?

GP: Well thinking long-term that's the thing life goes on. If there was someone with depression coming in with high blood pressure or obese we would still be addressing it. We wouldn't ignore it just because they have depression. The big thing is stigma in mental health and not treating their underlying physical causes because they happen to have a psychiatric diagnosis.

KP: talking about Smoking and Drinking. Would you happen to ask how many drinks or smokes a patient has per day or per week?

GP: we usually record that the first time a patient comes in and people are generally ok about smoking but everyone will tell you they are a social drinker. The first visit there is quite a lot of stuff to get done so unless something turns up funny in the liver function or blood test or something you tend to let that slide.

KP: I was thinking this could skew the risk factors a bit?

GP: I was stunned to find out how much people drink and it'll be the little old granny wearing pearls who you would think was almost teetotal. I would be like wow. Can be very surprised to find out how much patients do drink.

KP shows the GP the inclusion/exclusion criteria.

GP: It's ok

KP: We will give you a copy of the inclusion/exclusion criteria.

KP: what we have at the moment is a Google app. It will look a lot snazzier in a few months' time. So if you would like to read through it and see what you think of the content.

GP: So you have your basic demographics on the first page.

MP: We are including people's occupation and level of education as well but they might move later on because we have questions around people's cognitive reserve. It's been shown that education and employment levels have an impact on their cognitive reserve. So these might move to a cognitive reserve section

GP: if we had someone who is a professor and there MMSE is 27 we would start worrying what's really happening. However in someone else that could be an ok result.

MP: you don't have to read through them all it's just to give you an idea. They may be in a different order.

MP: This mood scale is based on the CES-D Centre for Epidemiological Studies-Depression. It's   a series of 22 questions on how people felt in the last week or so. If a patient scored 16 or over you might want to be worried. In that case we would be back in touch.

GP: That's fine no it's not a big deal if something shows up.

MP: there's a question about being diagnosed with depressed mood or depression. Ever been treated for depression?

GP: You would always tell them but you may know they have depression but may not put it in their summary. Every time they have a referral to hospital it comes up 1 depression. You do become aware that of people saying 2 we have a patient coming in with this symptom it must be the depression" when sometimes it's not. We ourselves wouldn't be aware of it.

MP: this is the page about medical health which might be of most relevance. Originally the profiler was designed for gps to put all the information in. then we realized GPs wouldn't have all this information.

GP: We would have none of that information

MP: It's moved towards the person themselves putting in the information but there may be some questions on the medical page that they may not have such as BMI or blood pressure.

GP: If patients get in contact before they come visit it is really easy for us to. There is a basic results bar we can click on it and print off in excel. Their cholesterol, blood pressure, height, weight, BMI.

MP: If we gave you a sheet you just printed up would that work.

GP: that's fine. That just takes a minute. All the electronic health records is just there in front of you.

MP: It means the patient has the information to hand.

GP: And they are not making it up

GP: need to clarify Q5 currently treated for high cholesterol and Q6 taking medication for high cholesterol. Could confuse a patient.

GP: 14 is one we are becoming a lot more aware of. Its only really exploded into our consciousness in 2007 when they changed the UK GP contract to start recognizing chronic renal impairment. So it's exploding.

GP: Are you looking for mini strokes *transient ischemic attacks* (*TIA*) that could cause vascular dementia? Patients under play the importance of mini strokes. It was just a mini stroke it was gone in 24 hours. It is a huge underlying risk factor.

GP: This is all very do-able.

MP: Should take about 15 - 20 minutes to complete.

MP: These are questions about cognitive reserve questions. Activities that people would do on a weekly basis reading newspapers, magazines, driving, leisure activities like bridge. Monthly going to the cinema volunteering. Then annual things like holidays and a few other things.

GP: A lot more detail than we do.

MP: the diet questions are based on the Mediterranean diet.

GP: I'm glad I am not answering this one.

MP: It's hard to get a good score

GP: (laughs) And its winter damn it. Great it's all extremely do able.

MP: do you have any concerns with the questions we are asking

GP: No

KP: Move onto the Risk Score. Here are some printouts examples of the risk score. We can say you're in the red of the gauge and want to bring it back to yellow or green.

GP: That the one that would really appeal to me. Example 2. It's easier to see. I think a headline score and maybe a histogram example 4 for different factors. I did the usmle exams a few years ago and you got your headline result but then you got what you got in each segment. You want to know the overall but the breakdown tells you where you can make changes.

MP: you will also get in the post a letter telling a patient your BMI and say if it is high or low etc.

GP: the VHI do something similar for overall health but they don't address dementia it is all for cardiovascular.

KP: Very little does really.

MP: the heart foundation now mentions dementia. We will send the risk score to patients would you like us to feed the scores to you as well?

GP: it would be very interesting for us to see what they are being told but also it give us time so we see it before they see it.

KP : What would feedback to you would be the score+ headline + breakdown. The personalised action plan will need to be reviewed as In-MINDD is a decision support system. We may be telling people to go out and do some vigorous activity and you may know there is a reason why they can't do that.

GP: Fine

KP: So the personalised plan would be sent back to you and once you ok it. Then we will send out plan to the patient

GP: Fine

MP: we have experts on board that overlook the information that we are given.

GP: to be honest I would never tell anyone not to exercise.

MP: it's one of the things we need to teese out.

GP: you are paying us to take part in the study so there is no problem

KP: WE would like to be able to send you a number of plans so they are not coming in drips and drabs.

GP: Even if they come in one at a time its not really a problem. We will just send them back with a sign here if you agree.

MP: the study is taking place in the Netherlands, Scotland and France. Because we have a different system where we pay to visit the GP its different here in Ireland. Early on in the project the other partners would suggest loads of GP visits and consultations but we have to pay for it here. What's your opinion on that?

GP: I would never charge if someone was to come in with just that. A lot of demographic information can be done by just leaving in a sheet and we can do that at lunchtime or after work. And leave it to be collected. Just discussing something (about the project) I wouldn't have a problem. If something highlights in it that needs on going treatment than that's something else. I was sort of thinking about it if it just generates one or two visits it's not much of a problem. There only going to be my patients at work that will be coming to see me so I will say to them that there won't be a charge for this.

MP: WE have to think further on this. We think we could do this with one consultation?

GP: It probably would be enough. To actually fill out the information that you require like bloods and blood pressure we would have had to see recently. Anyone with these risk factors would have had to be seen in the last year. If they are just coming back for their review annually you could incorporate it into that visit.

KP: Cholesterol was one of the things we were thinking about.

GP: People are really good at getting that done everybody wants to know their cholesterol.

MP: we don't want extra blood test to be taken just for this project.

GP: If they have been taken them as recently as the past year they are valid enough.

27.03

KP: here is the supportive information

MP: they will get their plan in the post but then they will be able to log onto the profiler to link into the supportive environment which will give them all this information.

KP: about things like exercising the brain. It will be presented in a much nicer form than this it.

MP: it is a first draft that gives the evidence behind why exercise and the brain are linked.

GP: We are great at treating numbers in this job but the overall thing that exercise improves is difficult to measure but really important. We will do a weight, blood pressure, cholesterol.

MP: how do we get people to (change?)

GP: People see the number improving and they think everything is better when it's not we just fixed the number.

MP: We will be measuring physical and cognitive activity in this which is probably a little bit different.

GP: Oh we don't. We just have our gut feeling about somebody.

GP: Sorry will I go on to these pages?

MP: Yes of course.

GP: another question what about having a pet in the family

MP: that's covered in our cognitive reserve questionnaire

GP: It's just the exercise, interaction, caring for something, etc

MP: The websites we are suggesting are national ones such as get Ireland active and there is similar questions on diet.

KP: would you recommend any specific websites to patients?

GP: I trained in the UK so we used the patient.co.uk website. It has phenomenal resources on virtually every illness you can think of and because it is the NHS they are not trying to sell you anything. They are not all whizbang. They tell you in your local area you can get this done.

MP: in terms of preventative health or promoting health is there any websites you would direct them to?

GP: I don't really I tend to say It's a bit like saving money we all know how to do it. Its just

MP: Get up and do it

GP: Yes you know people want this diet sheet for something. Well no you know the healthy diet. If you make things to constricted than people will just give up

MP: One of the things we talked about was trying to localize the information so we would give people information about classes going on locally.

GP: there isn't really. For older people yes falls prevention. But for the 40-60 age group I haven't come across many. There was some exercise referral programs, once someone shows me a referral form I say forget it we have enough paper as it is.

MP: so that's not something that you would generally refer people to.

GP: Generally no also some initiatives get launched and you don't know if they are still going. Here we are really lucky because we have long pavements without many streets

crossing them like Collins avenue, Griffith avenue. The amount of people that do that as a walk every day is quite good.

MP: We are still trying to tease out the social media part. Do you think peer support might be a useful aspect?

GP: I haven't thought about that. These are people who don't quite realize they have a problem yet. I don't if they would put in the time for it. If they are given the individualized plan they might just crack on and do it themselves.

MP: So you think its enough to have that information on the internet with the information on the risk factors that links into the websites.

GP: I can't imagine some of the people that I have in my head would even do that. Any forum I've seen online 2% of the people fill up 50% of the forum space.

MP: As people are following their plan can you see a role for yourself supporting them to do this.

GP: Oh I will remember who they were and be interested to see how they are getting on with it. At work we graph their blood pressure, weight and we can see it trending up or trending down or everything going wrong at the same time. I think when you see a visual like you would have on the headline, I think peoples brains work better that way

MP: We will be asking people to use it for 3 months and they will fill in the same questionnaire again. We can say look this is your risk score six months later after you have followed your plan. And we are looking to see if there is any change. It will be interesting to see how people respond to the information they get.

GP: They have done that in some 5 year diabetes studies where they come back 10 years later and the patients has just gone right back to doing what they normally did anyway.

MP: For the feasibility study we are going to have people in a control arm and an In-MINDD arm but we also be talking to them. TO see what encouraged people to do anything about the risk factors. Would you like access to the support environment yourselves as GPs.

GP: No we will see what we need to see on the report for the individual risk factors where they lie.

MP: would you need any other supports from us

GP: We wouldn't really think so we would just incorporate it along with the other preventative stuff that we discuss with them and hopefully they will have learned some stuff.

KP: Some of the other GPs we have talked to haven't been as positive in attitude towards this research

GP: We have a patient who was diagnosed with type 2 diabetes two months ago and he has absolutely changed his life around. Our practice nurse is in hysterics laughing at him it's such a change. He got a scare, he got a motivation and he has made a change. He is still in the obsessive stage about it but he has made an enormous change to his lifestyle. I could see some people seeing some of the risk factors, an orange light come on the dashboard and doing something about it.

MP: You think it might help some people in the future.

GP: Oh absolutely.

MP: the next stage is to some back to you to get 6 patients for a focus group. We need to think through some feasibility study issues. In the feasibility study we are looking for the practice to recruit 25 patients. Half for the control arm and half for the In-MINDD arm.

GP: That shouldn't be too much of a problem, we can pull electronic lists and we will know who is not too busy and agreeable.

MP: Good the people in the control arm will fill in the profiler but we will hold on to their plan till the end of the 6 months.

GP: Great

MP: We will be in touch with a letter you can send to your patients. We are looking for 6-8 people to come here (dcu) for a 1-2 hour focus group.

GP: People with depression don't want to say if they have it in a focus group situation.

MP: We won't be asking the participants about their health issues in the focus group

GP: Ok

MP: If you feel it may distress a patient it might be better to not put them forward for the focus group but hold onto them for the feasibility study.

GP : So you don't need any medical information from me for the focus group.

MP: No. Patients who take part in the focus group however may not be allowed to take part in the feasibility study. We have to discuss this with our partners to figure out what happened to these people.

GP: Great thanks very much.

GP 2 Interview Notes

GP	Location	Time start	Time Finish	Present
GP2	Cabra	10.30am	11.30 am	Muriel Redmond
				Kevin Power
				GP2

Transcribed Notes

Introductions

Muriel and Kevin brief GP2 on In-MINDD. GP2 is happy that he understands the project. GP2 has read the information sheet and consent form and signs the consent form.

Interview begins

Approx. Time 11.30

Topic 1: General Knowledge of, attitudes to and current practice regarding dementia deterrence

KP: What do you think about dementia prevention and risk analysis? Would you talk to your patients in midlife about dementia and how to prevent it?

GP: No I don't think that I would talk to patients about it. I talk to patients a lot about lifestyle stuff but it is mostly cancer risk and cardiac risk that people would be conscious of. So a lot of things actually cut across. We would have a general approach to people once they are over 40 of doing cardiac risk analysis. So we would generally like to know their weight, BMI, blood pressure, cholesterol and their smoking status and alcohol and we would encourage people to work on those. That would be mostly coming at it from a cancer risk or cardiac risk. I wouldn't be raising the risk of dementia as something and I may be wrong but my perception is that there is no proven interventions apart from general lifestyle ones where you can say do this and you won't get dementia. Ideally you don't want to raise a hair if you can't do something about it. So I suppose no to dementia specifically. But we would be bringing up a lot of the general healthy lifestyle advice that would cut across it. In terms of the specific things you're asking about in terms of social interaction and cognitive activity we wouldn't be. If someone came in and asked about it I might bring it up and often that comes up in families where there is a history of dementia in the family so they are saying what can I do? In that I would be encouraging people to be in clubs or taking part socially or doing things that kept them active mentally. Whether that is bridge or crosswords or Sudoku's or just talking to people you know. But we are not doing that in any systematic way.

KP: So no targeted specific services?

GP: No

KP: The next question is about the identification and recruitment of patients. Do you see any problems with targeting patients with high BMI, blood pressure, cholesterol specifically?

GP: No problem again we can find hypertensives from our system or we can take patients opportunistically as they present. Hypertensives and diabetics are coming in regularly. If you take people opportunistically you obviously have that bias of taking people who are interested in their condition and turning up. So you'll miss the people who are uninterested. We had a guy in this morning that last came in, in 2011 about his blood pressure and raised cholesterol and all the rest. Because he has to pay every time he just doesn't want to pay. So if you take an opportunistic sample you will miss him. From the point of view of designing an intervention that might be a big bias. We had a similar study of patient led interventions in diabetes about 8 or 9 years ago. Again it was the enthusiasts who showed up and volunteered to be involved and they are not your average. So that can be a problem with anything like this you know.

Time 5.10

Topic 2: In-MINDD

KP: We have interviewed one other GP. And what we are hearing is that the patients who are interested in their own health are the patients who will want to get involved. And not so much with the other people. With the system in Ireland it is different to our partner countries Scotland, Netherlands and France. These countries can bring patients back for visits a lot. With our system here we are trying to do it slightly differently as we are trying to steer away from as many visits as possible because the patient has to pay as you know yourself.

GP: Well it's a problem in both systems obviously there is a patient barrier in terms of bringing patients back because they will have to pay. In the GMS (medical card patients) there is a barrier as well as from a business point of view GMS patients already attend more than what you can reasonably defend on the fee that you get per year and you don't get anything extra for seeing them. There is no preventive pay within the GMS at all. If you were to strictly interpret our medical card it's designed on a reactive model only ok. And every GP that measures a blood pressure is paying for the privilege ok. There is nothing in the scheme (for prevention) it presumes the patient will come to you if they are ill. There is absolutely no funding for prevention except for the flu vaccine. That's the only thing that is actually funded. So there is a bit of a mismatch between what the administrator's view of what we do and what we see as our job.

MR: Just in terms of the clinical information which the patient will do the profiler by themselves with a researcher beside them. But they won't have knowledge of the clinical (inputs) like their BMI maybe but there blood pressure or cholesterol no. Would you have records for everybody or just somebody who appears to be high risk?

GP: Our aim would be any one who turns up we would be looking to have information we are not as good as we should be on BMI although we are trying to improve on that. We do encourage people to go anyone who turns up should have a blood pressure done in the last year. Cholesterol depends on the patient, they have to ring make an appointment go have the cholesterol taken we would have quite a good coverage of that for those who are attending but there are those people who just don't come near us and so we don't have any access to them. So of the people who are attending pretty much everyone will have blood pressure, we're not as good in terms of height and BMI.

KP: BMI is not so bad because the patient can enter height and weight and the system can provide BMI. The two sticky ones are Blood pressure and cholesterol.

GP: Again we can do it either way we can pick people who have those if there is information missing we can organise to get it done.

KP: The other risk factors that have shown up in the research into dementia are diabetes mellitus and chronic kidney disease or renal. Would you know much about them in relation to dementia have you heard anything about them in relation to dementia yourself?

GP: Not particularly, one of the routine tests we tend to do is renal profile and we send off a fair few people to the renal people to look after their kidneys. I'm not really aware that is a risk factor for dementia. Maybe there is a lot of cross over because a lot of these people would be high risk for cardiovascular problems.

MR: We have a lot of crossover.

GP: Certainly that is my approach to it but I wouldn't be saying that to people particularly. Maybe in terms of stroke prevention if you say that dementia is one third vascular and maybe another third mixed. There is a vascular cause to 50% of people or a significant vascular factor. Again I couldn't claim that I am doing this to prevent dementia I am doing this because I don't want your kidneys to fail or I don't want you to have a heart attack or a stroke because you are at a higher risk of those. I can't say I am doing it at the moment because I am trying to prevent dementia.

KP: Do you think you would have much of an idea of how physically active or cognitively active or inactive a patient would be?

GP: No we are not asking those sorts of questions routinely. I don't even have, while I would have an approach to physical activity I would be doing that in relation to obesity management or diabetes or cardiovascular disease. You would be aiming to get people up to 30 minutes four times a week of exercise. Cognitive activity apart from very basic stuff I don't think I don't have any easy check list in my head that I go through with people or apart from general stuff of encouraging people to join whatever local societies or be involved. I don't have any other interventions that I would be telling them this is good for you to be doing.

Time: 12.27

KP: Is your communications with patients mostly with letters and phone calls or would you email or text message.

GP: We don't email and we don't text. Phone calls letters or consultations yeah.

KP: We can show you some of our content for the profiler now

MR: Please read through and ask any questions or stop along the way

GP: So somebody would be completing this online?

KP: Yes at the moment we have a Google app, which is just simple tabs and this is the content for it. It will look a lot snazzier in a few months' time but that is the bones of the content. If anything sticks out at you let us know.

GP: For years of education I'd think how many years did you spend in school? Or something like that or even just an explanation on that. Again we would have a lot of people of low educational attainment and they might not even fully get what you mean there. So this is stuff that is just lifted directly from the definitions so you can't really change that.

(Mood questions)

Where are these from?

MR: So this is the mood score.

GP: Is that the 20 items. Is it a standardised mood scale?

KP: Yes it's the CES-d I think. It's standardised and validated.

GP: So this is your height, weight and cholesterol ok. So if people answer no to these is there a follow-up where they will look for that information from the doctor. How do you plan to deal with people who don't know the answers to those questions?

KP: That's a good point.

MR: There should be a don't know option for some of these.

KP: What comes out of this is a risk score and action plan.

GP: Yes but if these are not answered can you still get a risk score.

KP: We will look into this.

GP: I would have a lot of people who would ask what is my blood pressure and cholesterol. But they won't remember it. All they will remember is if it was a problem or not. Often people take it away at that level, the patient would say I have a cholesterol problem but they wouldn't be able to say if it is 5.5 or 9.5.

KP: How we envision it working for In-MINDD since we need to input blood pressure and cholesterol is that we would have an information sheet and for each patient the doctor would print it off. It would contain cholesterol, blood pressure and BMI

GP: That's what I was going to suggest. We could fill that in for them.

KP: So then the patient has up to date real information.

GP: That would be no problem for us anyway.

Time 21:00

GP: Again it's the serving sizes. You have a regular burger or you have the quarter pounders which are actually 250 grams or more. I don't know whether as a general rule.

KP: When it's presented on the screen a lot of these will have scroll-over and drop down menus that will explain how much is in a serving or how many spoons of (veg).

GP: Ok. So I use, when I'm talking to people about dinner quantities I talk about dinner plates. (GP shows researchers an example paper plate). I mark off the inner plate, nothing on the outside circle and vegetables there and carbs there and meat there. That's the way I approach it with people. If you are trying to translate that into grams I suppose spoons could be more accurate.

MR: We will use spoons because we'll have to change it slightly for people; if people come out as obese maybe there will be different advice.

GP: What you will find is there are different perceptions; I don't eat anything I don't know where it comes from.

MR: Portion sizes might be a problem there. Again this is just a draft.

GP: Some of that is layout stuff again I don't see that there is anything insurmountable in it. If people can do it in their own time then they are not under pressure. What you're working towards is something that people would complete at home?

KP: At home yes, the only thing that they would need is the hand out about blood pressure/cholesterol they could complete the rest at home. When completed they will get a dementia risk score and also there will be an action plan. As it's a decision support system these will be sent to a GP to OK them. Just in case we were saying they should be doing more exercise.

GP: And there is a reason why they shouldn't

KP: Yes the doctor will get sent the action plan and risk score. The doctor just has to ok them or not. If they are not ok they will be sent back and changed around. So that is the next time the doctor would see the action plan.

Note MR Gives the action plan example to the GP.

MR: So this is what we are thinking of working off now it hasn't been finalised. So when people fill in the profiler they get a score and image like this.

Note: GP shows researchers a cardiac risk chart

GP: The one we are most used to using is this one is a colour coded one for cardiovascular risk. So you go from non-smoking young women up smoking to high cholesterol and hypertensive men and the colour goes up with that. We have an intervention level of 50% so generally you roll someone up to 60 and see if they will be at 50% and if it is the case we say that we have to get your blood pressure, your cholesterol and your smoking habit dealt with. The cardiovascular risk charts are something that pretty much every GP is familiar with.

KP: What is that risk chart called?

GP: It's the 3rd join task force for blah blah. It's the European heart journal. Cardiac risk. It's the European guidelines on cardiac risk.

KP: We want to present it in a way that won't scare anyone off.

MR: Yes and that's user friendly. So basically a person will fill in this, they will get an overall score for dementia risk or whatever we are going to call it. And underneath we will have some sort of bar chart or something similar that will have their high risk factors. So you might score quite low on exercise, your diet could be poor or you could have high cholesterol. What we are saying to people is that you could have scored high in 3 or 4 maybe just one. We are trying to suggest that you pick one. So if you pick smoking we suggest that they try cutting down, we will give them options like give up with the aid of patches or just cut down. So we provide them with extra supportive information and ask the patient to some back to us in a month. If they have given up great, if they have cut down even one a day we can say will you try 2 a day. If people can't do that for whatever reason we will say ok maybe you can increase your exercise. So then we lead them to information on smoking cessation, dementia, how to increase your exercise. We are using national sites like getactive Ireland and we have diet and nutritionists supporting us. So the information we give to people is all above board. I will send you the information so you can see it. We are trying to ask people to try change one thing at a time.

GP: How do you keep people engaged? When people fill out the thing and get a plan back that tells me I really should do this and this and say Whoa not going to open that page again.

MR: Well the message will be to pick one that is doable also we will build in a text alert that once or twice a month will say how is your exercise going?

GP: Run keeper does that to you. If you haven't been running for a month it says what are you at?

MR: Overall we are getting people to come back after 6 months to retest them. If they come back to it each month overall there won't be a huge difference but if it is

incremental, I've started to run a bit more. What sort of advice would you give if someone said they want to get fit?

GP : The message they will get here is smoking is 10 times more important than anything else so if you are going to do anything to pick smoking first and we would run through that with them. Generally people are more interested in what you can do for me unfortunately. So they want us to fix them. So then you're into cholesterol management and blood pressure management. We use diet sheets mainly. These ones here (*note: shows researchers diet sheets*) are the main ones we use. Some of them are the Irish heart foundation some are provided by pharmaceutical companies. There is that whole difficulty in moving away from it's somebody else's problem to actually taking it on board yourself.

KP: In-MINDD is trying to promote taking care of your own health improving your own health to offset these types of things. One thing we have been trying to build into it a social media aspect where they can talk on boards to other patients using In-MINDD. To help each other to try cut down smoking or improve exercise what would you thing about that.

GP: I think that again there is the enthusiasts and people who really want to try do that sort of stuff so it's not everyone. There would certainly be a subgroup but I'd be guessing it's not more than 20% of people. There is lots of stuff you see around like hotlines and you see The Mater (*hospital*) has a smoking cessation set up there. The big problem is that everyone can be enthusiastic. The sad thing for health professionals is that for most people their health is not their number one worry. People don't worry about it as much as we might think that they should. That's always the challenge you want to make people mildly anxious so they will change but you don't want to push some people who are already highly anxious with red danger signs. What do you do then? We do get people in their 60's and 70's who say I'm worried about my memory. We give them the basic MMSE and they are normal but they know something is wrong. In my experience they come back 3-5 years later and they do have dementia. For people who are worried about dementia I'd be thinking what can we do here? I'd be mostly just concentrating on the cardiovascular risk. But if there is other interventions I can suggest to people, I can say to people you need to be getting out and meeting people or doing more exercise.

MR: That is our challenge as well to try get people to engage in the whole process.

GP : Again there'll be a range some people you'll be trying to beat off because they will be filling out here assessment every week or people won't go near it. My experience of lifestyle interventions is that it's a minority interest but it makes a big difference if that minority is 20% or 30 %. So what you have to do is

KP : Build on the minority?

GP : Yes

KP : We have some supportive information can we send a small portion of it onto you and if anything sticks out if you want to send it back in an email.

GP : Sure

MR: There is diet plates ,the food pyramid and not pushing people but edging them towards a more Mediterranean diet. As research suggests they have a lower risk and for all sorts of reasons.

GP: I suppose we'll just have to move to Greece

MR: And more information on cutting down on portion sizes. For obesity do you offer any specific advice or programs.

GP: We give them diet sheets here, if they have diabetes or are over 65 they can get access to the community dieticians. It's a very variable thing and depends on which primary care team are you are in and whether there is a dietician in or not. We send most people to weight watchers to me that's the best. There is a new commercial group set up in Phibsboro called Health Reach. It's expensive you pay €400 or €600 for a program but it is an intensive lifestyle intervention program that would take on people with diabetes, cardiovascular disease and actually work with them to bring down their risk. They do good stuff and it's a very intensive program, the problem is for most of my patients it's not really a realistic option because most of them don't have enough money for this week's shopping never mind what health reach are charging. It is good.

KP: The next step is for us to draft a letter we can send to you and print on your headed paper. It tells the patients about In-MINDD and that we are looking for people to take part in a focus group in DCU. So basically we would need you to target some patients that have 1 of the 10 risk factors and send the letter out. And we will take it from there.

GP : If you are looking for a relatively small number

MR: Its 6 to 8.

GP : I'd probably just do that face to face it works better I think.

KP: The focus group is 6-8 and the feasibility is 25 patients

MR: This is for patients to see the online tool and see if there is any problems with usability. There is an assumption that everyone is online.

GP: Our practise is heavily GMS so we have significant literacy problems significant lack of access. I talk to people about it in terms of applying for their medical card if you apply online it's a really quick process and it works. A good third or so of people would say I can't use computers, would have difficulty navigating. So it's higher than you might realize. I sent a lot of people to citizens advice or local partnership offices or the Dublin city libraries will often help people if they don't have a computer themselves or they need access. It's a motivation thing sometimes people just feel embarrassed, you know everyone knows how to use computers. Even mobile phones a lot of people would still be using a basic phone as they haven't got themselves over that hump.

MR: That's an interesting finding in itself

KP: Some of our other practices would be quite middle class so it's good for us to spread our demographic.

MR: We would hope for a gender spread as well.

GP: If it works on the smart TVs is my hope that once it's on telly it'll be grand. I don't know whether people are getting those smart TVs or not. You come from your own background and sometimes it's hard to step into other peoples shoes. We meet lots of people every day who never read a paper, don't do anything online. Collect their money from the post office so they don't actually even use the banks that much. There just operating at a completely different level of using information or IT. And once you're doing it yourself it's very hard to comprehend how someone is getting through their day to day. That may be a problem of both education and access.

MR: I think that's interesting too I had thought about that at the beginning of the project. The Dutch partners were able to look up access and say its 80 % but it's not like that here.

GP: There is a huge social gradient. Income wise and education wise. If you're talking about people under the age of 35 there is no issue. If you're talking about 40-60 cohort there will be a significant number who never had to use computers and have missed the boat.

MR: Early school leavers. It will be interesting to look out for that. Is there anything else Kevin.

KP: I will be in contact next week and will send on the letter with the information pack for patients. I'll leave some business cards for patients.

GP: my email is ▮▮▮▮▮▮▮▮▮▮▮▮▮▮

Finishing remarks

GP 3 Interview Notes

GP	Location	Time start	Time Finish	Present
GP3	Marino	1.30 pm	2.30 pm	Maria Pierce
				Kevin Power
				GP2

Transcribed Notes

Introductions

Maria and Kevin brief GP3 on In-MINDD. GP2 is happy that he understands the project. GP2 has read the information sheet and consent form and signs the consent form.

Interview begins

Approx. Time 1.30 pm

Topic 1: General Knowledge of, attitudes to and current practice regarding dementia deterrence

MP: Most of the risk factors that you would be collecting information about such as height and weight you would know about. The ones that you probably wouldn't know anything about would be there cognitive activity?

GP: Yeah

MP: Or their physical activity

GP: Yeah

KP: Social Interaction

GP: Some I might just because I live I the area, I might see them out and about and I'd know it from that point of view. It wouldn't be necessarily stuff we have sat down and recorded with charts and that kind of stuff.

MP: That's ok what they will be doing in the profiler is filling in that information themselves. And what we might ask you to do, for people who are filling in the profiler would be to give them some of the information. Cholesterol level, their blood pressure or BMI if you have it to hand those types of things.

GP: Yeah, ok.

KP: SO we know that they have up to date accurate information for the clinical inputs. Which would pretty much be BMI, blood pressure and cholesterol. And even BMI, we're going to ask for their height and weight so that would calculate it for us. So the

main things are blood pressure and cholesterol. The way we see that happening is we give each GP a hard copy which the GP can print off containing a patients BMI, blood pressure, cholesterol. The patient then will have this information and can update it at home or when they are updating the profiler.

GP: And if you need to recruit patients for this? Is there certain things you're looking for or is it a random thing.

MP: there are two stages to the process and what we have asked you to participate is the first stage. Which is really trying to get yourself and the patients involved in helping us to design the whole profiler and support environment and getting some feedback on it. That will be a focus group interview with the patients and we need about 6-8 for that.

GP: oh right ok.

MP: Later on there will be a feasibility study which is bigger we will have about 6 GP practices involved and we will be asking the GP practices to recruit about 25 patients.

GP: There are 500 patients in that age group registered. Now how many of those patients are active or not I don't know. They tend to be of an age group particularly the 40-50 year olds who probably aren't in that often. The women have stopped having their children. For the 50-60 age group you would have a better idea but for that age group you might not. So while there is 500 patients that might actually be a 100 (active).

MP: and would you be able through your database to be able to identify the people who would have some of these risk factors

GP : Yes we should do, If we have been good enough at putting the information into the system. I can certainly do a trawl of who is on anti-cholesterol medication, or anti-hypertensives, or looking at their past medical history and things like that yes it should.

Time: 3.33

MP: Ok. The other approach we were thinking of taking was putting up recruitment posters in the practice so people might see them and say actually that's me I'm not very cognitively active. It might be good for me to participate. Would you be open to that?

GP: Ye that would be fine.

KP: We were talking to another GP today who thought it would be good to do it face to face. If he had a patient in the age group who he thought had the risk factors.

GP: Ye that would be one way of doing it. The other thing is we have the website. I could always put it up on the news page. I'm not sure how many people actually look at it.

MP: They probably do for opening times and stuff like that

GP: Yeah I could certainly put that up there as well.

MP: right OK

KP: We have the inclusion/exclusion criteria here. If you want to have a look at that it's just the eligibility criteria.

GP: Ye OK as I said the cognitively or physically inactive ones, the other stuff we probably do have a reasonable

MP: Possibly by the advertisements on the website we might be able to find people in that or they may be overlapping as well someone who is very obese may be physically inactive

KP: most of the overlap with cardiovascular risk factors.

GP: Ye I suppose it's the cognitively inactive ones that would be a bit more, and it's how you define that? You know how do you define someone as being cognitively inactive is it that they never pick up a book and read it or is it?

MP: it's a mixture of those kinds of things, engaging with people as well through going out to the cinema and theatre even looking after children

KP: Or pets

MP: Or pets, and then education and your job would also give an indication.

GP: I'd like to say that I don't qualify apart from the age criteria

MP: depression is one of the risk factors but we don't want to include anyone in it who may be caused any type of anxiety.

GP: if they are stable and on treatment they can do it?

MP: once it's not a major episode of depression they can. If it's a mild depression that wouldn't be a problem. Depression is one of the risk factors and maybe there is things that we could link them into that might help them.

GP: Absolutely yeah.

KP: this is just a topic schedule for the interview but we will try to keep it as conversational as possible and a lot of it will be showing you our content for In-MINDD and actually just seeing if you have any problems with it. One question we have been asking other GPs so far is we are trying to promote healthy lifestyles with a view to trying to offset your risk of dementia in later life so would you know much about that or talk to your patients about their risk of dementia in later life.

GP: probably not their risk of dementia I would be more likely to talk to them about their cardiovascular risk rather than actually their risk of dementia. I would try to get them, probably cognitively active no but I would try to get them physically active. Try to lose weight, do all of those kinds of things. More so on the depression I would say to get out there in groups, without thinking about it without formally. Certainly I would never say to them the best way not to get dementia when you get older. That wouldn't be a conversation I would have. But I would encourage.

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Time 7.50

MP: When you talk to participants do you mention that these types of things may put you at risk of dementia in the future?

GP: Ye I suppose, when I'm talking about blood pressure and things like that. I would do to an extent. Probably not as much as I should but yeah.

KP: You don't want to be too negative.

GP: Ye it's like you're telling them that you could have a heart attack or you could have a stroke and the worst thing if you have a stroke is that you might not die. So all that kind of stuff you are already bombarding them and you say you are going to become demented too. It is not necessarily something that you want to do.

KP: We're not saying that you should be doing that, but we are just trying to get your opinion on it.

MP: I suppose we are more interested in what you say about the risk factors for dementia as opposed to whether you're communicating the message.

GP: I'm probably not very good, it's more when you have somebody in who I am worried may be showing symptoms of dementia. Then I would be looking at it retrospectively perhaps more than actively. At the same time the risk factors that you have shown there I would be treating those as I go along so inadvertently doing it without realizing that I am.

MP: yes that makes sense.

KP: very similar to other GPs

GP: it's probably not something that is promoted to us that much. What am I 15 years in general practice, it wouldn't have been something we did a huge amount about.

MP: As the research is emerging more and more there is a stronger evidence base that all these lifestyle factors are a risk of developing dementia

GP: yeah at the time it was either you had Alzheimer's or you were just a bit forgetful as you got older. I suppose all the vascular dementia stuff has come out more recently.

KP: so identifying patients for the focus groups and feasibility study that will start in July. What we will ask you to for the focus group is to identify 6-8 patients with one of the ten risk factors and that suit the eligibility criteria which you will have. So could you see any problems identifying patients?

GP: No I would certainly identify them. But whether they were willing to take part.

MP: would you be happy to send out a letter that we draft?

GP: ye but I would be more likely to ring them actually. Letters tend not to work I would be more likely to ring and tell them I am going to send you out a letter. That would be more likely to do it.

KP: the way we were going to do it is to send our letter to GPs. The letter will them about the focus group and tell them about In-MINDD. It will say the focus group will be help in DCU and ask them to come along which we will send to you and you can print on your headed paper. There will also be an information sheet which will them some more about In-MINDDD.

GP: Are the focus group times during work hours or is that in the evenings?

MP: We have to be flexible because we are aware that people in this age group are working. Usually what we say is at the convenience of participants. We think that DCU will probably be convenient enough for them.

GP: Ye

KP: it would be very handy for us especially if we are going to present information on computers. We can be all set up there and have some refreshments and stuff there.

GP: Ok fair enough.

KP: I am a PhD so if they want to do it a 9am they say jump I say how high. (Laugh)

GP: and what's your background

KP: Psychology, my masters I did a similar study on brain training which was a lot of focus groups. Trying to get people to do things that they don't really want to do,

GP: Just like Medicine

KP: so the clinical aspects that In-MINDD will look at include BMI, total cholesterol, cardiovascular, heart disease, blood pressure, diabetes mellitus, chronic kidney disease, family history of dementia and cardiovascular disease. So they are the main clinical ones we are looking at. Would renal be coming up in your consciousness as a big factor these days.

GP: Ye it's funny because I was looking at doing an audit on it myself this year. Some new guidelines have come out to say we are over diagnosing chronic kidney disease. We are probably putting people into clinics that don't need to be there. So I said I'm not going to do that. But ye it would be something that I am aware off yeah.

MP: I don't think it would be in the top 10 because I think they want to look at some more of the research that has been done because the jury's out. We will just for the study be asking them about kidney function.

GP: and the family history of vascular dementia you are going to find that hard because they won't necessarily know.

MP: There will be a don't know box

GP: oh ye she had dementia but I don't know which type of dementia it was we were never really told half the time you would be amazed how many people don't know.

MP: Even people who have been diagnosed themselves haven't always been told.

GP: even some of the letters you get back from the clinics you would be unsure of what the actual diagnoses is sometimes.

KP: so here is a paper copy of the questions.

MP: this will be online

GP: so I presume just in terms of data protection this is all encrypted.

MP: yes we will be seeking ethical approval from DCU for all of that so ye. So we will have to comply with all the ethical guidelines and data protection legislation. So we will have an id number for all the people. We will keep their names and addresses separate from any information that could identify them.

GP: you don't have house wife down there as a job no.

MP: We have got it comes in somewhere.

GP: It's just about whether you're working

MP: its paid employment as opposed to

GP: looking at the home and family there that says

MP: so this is basically the CES-d

GP: seeing how depressed they are?

MP: it's really about their mood we won't be giving them a diagnosis of depression. If they get a particularly high score it wouldn't exclude them but we may suggest they go back and visit their GP as well as what's on the website.

GP: Let's say we haven't got a record of their cholesterol do they need to get that tested.

MP: No they don't. It's only if the information is already readily available. They would not need to be screened for anything they have not already done. If it hasn't been tested then the GP sees no need for it to be done. So we are not going to expect them to go get a test for that. In that case we just presume its ok unless they decide themselves to go get a cholesterol test. Which may happen you know.

GP: I'd put irregular heart rate in there in terms of heart disease and cardiovascular. They might only know that they have an irregular heartbeat but they don't have any heart disease.

GP: See here where it says chronic kidney disease or abnormal kidney function results. If they have been told that then you should be able to get that result. You might not tell

someone they have kidney disease you might say the kidney function was a little bit off we should check it.

MP: We have some experts on board. So we might just ask them what's the best way to ask that question. We will certainly have a look at that again.

GP: if I am reading it I will not necessarily say to my patients you have chronic kidney disease. So they might say no to that but might have it.

KP: it's just more if they know they have had some sort of kidney problems

Time: 20.00 approx.

GP: how many hours of physical activity is considered?

MP: I have the definition in there so it will pop up as the user answers the questions.

GP: But in general is it supposed to be a certain amount of physical activity a week.

MP: Well they have both moderate and vigorous it should be 20 minutes 3 times a week. Where you have difficulty speaking because you are so physically active.

GP: judging by the amount of people out jogging these days. It's a bit addictive.

MP: yes it is a lot isn't it.

KP: For all those there will be scroll overs. It will explain

GP: they will be able to do this thing on their iPhone or iPad.

MP: Well no they will be doing it in our presence so we will need to meet with them and complete it then.

MP: we have informally tested it out and it takes about 20 minutes to fill out. So I think we can quite quickly go through it.

GP: it seems fairly straight forward

MP: probably trying to calculate the amount of flights of stairs you do.

KP: there are probably a few things in there that are a bit too specific. But that's what research is all about. So the patient will fill that out and the patient will get a dementia risk score. Which will be called something more positive. So what will happen then is that an action plan will be produced. So the score will tell them let's say they have high blood pressure, are obese and smoke. The action plan will say you have 3 factors you can try to do a bit of work on these. The action plan will say pick one of the 3 the one that you think you can work on the best and this plan will help you to bring them down. So we want to send that then to the GP the GP has to Ok it as it's a decision support system so if let's say someone has a heart problem we may be suggesting vigorous activity you might say no that's not for them. If that went to you then you would get

action plans and have to ok them or not. If they are not ok it gets sent back to us and we would have to change the specific risk factors.

GP: if you don't ok are you saying listen if there is 3 actions 2 and 3 are absolutely fine but this person would not be able for 1. They have got severe arthritis so they can't run a hundred hours but they might be able to swim.

MP: we would be suggesting different things for different people with differing levels of ability. So we won't be telling everyone to go and start running the marathon. It would be something mild like walking. Or maybe joining the yoga class or something like that. But the information to begin with would be quite general and cover many different types.

GP: OK

KP: so here are a few examples of ways we might present the risk score. *(Presents score examples).* If they are in the red for some factors maybe we can bring it back to the yellow. So there are a few examples of ways we could present it.

GP: I think guys would like those they are very male. That's my first impression they are all things from cars. You know I don't know how you could do it any better but that's what really strikes me. It's very male.

MP: that's the first time we have heard that.

GP: it does make sense in terms of.

KP: these are just examples of what it might be.

GP: something like a traffic light kind of system. Or there not so bad if it was more like a kind of a pie chart.

MP: well it will be you know.

GP: it just looks like dials.

KP: We were thinking that would be your headline and then the next image would give you the breakdown. Which would say your smoking is high so maybe we can look at that but your weight is fine.

GP: so focus on some positives as well.

KP: yes you're doing well

GP: unless they are high on everything.

 MP: but then we will allow them to select an area that they would like to work on. Just one risk factor so if that's smoking it will be about trying to cut down. I suppose the key message is to try and change one thing at a time. Instead of bombarding them with too many aspects of their lifestyle in one go. What we were thinking of doing is sending

both the risk score and personalised plan to the GP. They could come then and discuss it with you.

GP: ye fine

MP: (ask the GP) how would you interpret this? What kind of supports are there?

GP: If they came in for that. What happens if someone comes in just to talk about that? I'm charging them for a visit.

MP: this is a big issue. This is happening in four countries and we are unique in respect that we charge people for visiting their GP. So it's an issue for us but not the other countries. So that's something we wanted to tease out with the GPs as well. So if people did come would it be as part of another visit.

GP: Well its fine if it's part of another visit. But if they specifically come in just for that? If its part of another visit you don't charge them any extra. But you would charge if it was to talk just about this. But you could do it over the phone I suppose. That would be fine. But if they wanted to come in there could be charge.

MP: Which is prohibitive. That is important for us to hear.

GP: it's just because we are in a partnership here so if I see someone and I don't charge them that's taking money out of the

MP: The Pot.

GP: But there's ways around that as well.

Time 30.06

MP: There is going to be reimbursement but its not really to cover the cost of the consultation. More for other aspects making phone calls and sending out letters that type of thing. This interview and that type of stuff. But it wasn't to cover the costs of people's visits to GPs.

GP :Yeah yeah

MP: but it is something that we are very conscious of and aware of.

GP: Is that something else the other GPs have brought up?

MP: there's differences some GPs have said they won't charge anything but that's up to the individual GP to decide if they want to do that or not.

GP: it's probably something we could look at but I'd have to have to discuss it with (partner) before I could say I will do it or not.

MP: We're not asking GPs to do that

GP: absolutely but it's a consideration because people are giving their time to take part in the study they would feel so why should they incur a cost to take part in the study.

MP: Absolutely yeah

GP: the risk is that they will come in just to talk about that and you are giving them that for free and oh but sure by the way doctor then they will try to get the rest of the consultation for nothing afterwards.

KP: they might do that every week for a few months then.

MP: that is something we will have to think about. Obviously there won't be a cost for this part of it with the focus groups.

GP: obviously no it was just something that struck me.

MP: It's a legitimate question and concern yes so we were aware of it ourselves especially its interesting comparing ourselves to the other partner countries who don't have that issue because of free GP care. I think it's opened their eyes to how things work in practise here as well.

GP: Quite different. As I say if they are literally coming in to talk about that I probably wouldn't charge them but the risk is you do that once and all the other things get added in and you can't charge them because it was you know.

MP: Ultimately I suppose what we are trying to do is to imbed this type of work in everyday practice you know so that it wouldn't be that they are coming in to get there dementia risk score but as you are treating patients you would be aware of this. As you are doing at the moment in relation to cardiovascular health. In the long term it wouldn't be a cost.

GP: So for this part of the study it might be you know.

KP: there is the action plan and the supportive environment. The supportive environment gives the patient information on their particular risk factors so we have some of that information.

MP: That is really just in relation to exercise it give the guidelines on what is vigorous and moderate activity are all in there so they will have access to that type of information. So basically first of all it's to give them some idea of the evidence in relation to exercise and brain health and that kind of stuff.

Note: GP is given the supportive information hand out for review

GP: I thought I was physically active. (Laughs). That's actually very good that couch to 5k they have great podcasts that you download onto your phone. I started running about 2 years ago and I hadn't done it since I was in college. It tells you how to stand and how to hold yourself and all that kind of stuff. They're great.

MP: Is there some online supports that you would recommend your patients to go to at the moment.

GP: yeah the couch to 5k would be one, myfitnesspal, patient.co.uk you can register with them they are very good. They would tend to be the ones I use most often just in terms of getting up and out. I think they would find them quite useful.

MP: and in terms of obesity or depression?

GP: obesity ye myfitnesspal because you can do a calorie counter and things like that on it if they have it. Weightwatchers and slimming world and they have support groups to try and help. We have a reasonably good dietician service. We refer them to a dietician sometimes. With depression not specific kind of stuff book more so self-help books more than necessarily online tools, tell them to go down to the library. There's books down there I would tend to recommend. There's a kind of CBT that you can do online and stuff like that but you know for those who can't necessarily afford see a councillor.

MP: Ok and in terms of the management of heart disease or blood pressure?

GP: for blood pressure, they all tend to come together, but for blood pressure I would tend to send them to a dietician to check their salt intake and diet and that kind of stuff and to get out and be physically active. You know similar things, a lot of it would be similar to diabetes, weight management, being physically active, looking at their diet again. A good program that they run here for diabetes patients called expert they run 2 or 3 times a year. I have had a few patients who find it very good. Here is the hand-out.

http://www.hse.ie/eng/services/list/2/PrimaryCare/pcteams/dublinsouthpcts/dunlaoghaireglasthulepct/xpertdiabetes.html

MP: do you mind if I keep that.

GP: it's the only one I have

MP: no problem ill look it up online and I'll be able to get it. It's under the HSE is it?

GP: it's quite a good (program) that's the email if you want of the girl who runs it there.
██████████████

MP: great thank you very much.

GP: they run it twice a year/3 times a year in different parts of the city. It's like a group kind of a thing they talk about healthy eating, activity, how to manage your diabetes all that kind of stuff.

MP: I suppose what we could do is to make people aware of this kind of thing.

GP: and they self-refer to it so they can just ring and sign themselves up for it.

MP: there is also the physical activity referral program the HSE runs. I know one of the other GPs brought it up but he doesn't refer his patients to them because you need this referral form and stuff like that. I'm not sure if it's available in every area.

GP: you see some things are available in some areas and not in others. I haven't heard of it usually if it's available. The HSE do run smoking cessation classes and stuff like that. A similar kind of thing and stress management they do a stress management thing as well they have some reasonable initiatives dare I say that out loud.

KP: In-MINDD is about directing patients to services that are already fit for purpose with specific risk factors in mind instead of trying to reinvent the wheel.

GP: Utilize what's there

MP: would you think that most of your patients have access to the internet and use it.

GP: Most of them certainly in the age group you are talking about yes the vast majority would. There would be very few any more that don't. Maybe as you get to the sixty they mightn't but certainly any that are at work or do anything like that would. Most of them have smart phones. We'd have a reasonably high level of education in the area.

MP: OK and is there any other feedback you'd like to receive about patients or their progress?

GP: I suppose just their progress, you not doing an actual dementia score on them as such it's just their risk score?

MP: they will have an overlap dementia risk score and that will be between 0 and 20 depending on the risk factor and some of them would have a higher risk than others according to their factors.

GP: trying to bring that score down. The interesting thing to see then is what percentage of those go on to develop dementia.

MP: Yes but there are also age and gender and genetic factors. That have an impact as well so

GP: and you are looking more a multi infer for vascular dementia.

MP: No not just vascular dementia because these risk factors have been shown for all types. And then a lot of people do go on to develop a mix of both Alzheimer's and vascular dementia. And then you have the younger people who have really high intake that go on to develop Korsakoffs. So I suppose it affects a lot of different types of dementia you know. So we are not just looking at vascular dementia but the all different types of dementia. But they will get their global risk score and then a breakdown of where they fit in each of the different areas. So they will see how the global risk factor is made up of the different risk factors. What we hope is for them to fill in the profiler 3 months and then 6 months and see if they have any chance of bringing it down. It might be quite difficult in some areas than others and then what activities are they taking up? Have they been prompted to do anything by virtue of this?

GP: It's interesting

MP: So that's I think everything.

KP: That's pretty much.

GP: so what do you need me to do then?

KP: we are just finalizing our letter for the patients for the focus groups so we can give you a call when we have it ready and send it our letter if you want to put it on your headed paper or do phone calls there will be an information sheet as well.

GP: I will call first and say I'm going to forward you on the letter. I think that will work better. If you just sent the letter people would thing whats wrong with me?

KP: the last thing we want to do is frighten people. That will be the next phase trying to get people for the focus groups and trying to keep the risk factors In-MINDD.

MP: and trying to get a spread of people

GP:You're looking for how many?

KP: 6-8 for the focus groups. 25 for the feasibility study starting in July.

GP: ok and the initial 6 or 8 are they allowed to follow on or do you exclude those?

MP: for the feasibility study we are going to divide people into an INMINDD arm and a control arm. So because these people will be primed about the information they have seen we probably think its best that they don't participate in the feasibility study. But we think that we let them go through the process anyhow but we will just not use their data. So they will go in and get their risk score and get their data and access the supportive environment.

GP: you kind of have to, you know your great thanks for helping us off you go

MP: for ethical reasons it wouldn't be right to do that. So we are going to allow them to participate but not to use their data. So is there anything else you would like to ask us?

GP: no that seems fairly straight forward

KP: I have some supportive materials about IN-MINDD here for you and business cards

Note: Closing Remarks and Interview is ended.

GP 4 Interview Notes

GP	Location	Time start	Time Finish	Present
GP4	Marino	1.30 pm	2.30 pm	Maria Pierce
				Kevin Power
				GP2

Introductions

Maria and Kevin brief GP4 on In-MINDD. GP4 is happy that he understands the project. GP4 has read the information sheet and consent form and signs the consent form.

Interview begins

Approx. Time 2.00 pm

GP: Ok so my thoughts of it were yeah it's an interesting thing and you seem to have changed what you wanted to you talked about 6 to 8 patients

MP: well initially

GP: and then you were talking about 15 or more or something like that.

MP: yeah for the co-design piece as we are calling it we want to get 6 to 8 patients of yours who would fit that criteria. Kevin is conducting it so he will tell you more about it.

KP: ye basically we are looking for 6 to 8 patients for a focus group. So we are interviewing GPs at the moment to let them see the kind of content we have in the In-MINDD online program. And then we want to get feedback from some patients so some patients in midlife that have one of the risk factors that we are looking at. The focus groups would involve the patients coming into us and we would show them the In-MINDD profiler and the types of questions and we will ask them for their feedback on it. So what do they think of these types of questions, what are their attitude to becoming healthier with a view to reducing their risk of dementia in later life. So it's just an hour maybe an hour and half focus group with 6 to 8 patients.

GP: and where would you do that?

MP: we could do it in DCU; it was more convenient to do it somewhere more locally we could do it. What we usually try to do is do it at the convenience of the people who are participating.

KP: so far most of our participants are coming from the area near to DCU. So over there it would be easy enough for them to get to DCU. Over here it could be a bit more awkward so we could try and get a room somewhere around here.

GP: A thought might be St. James's

MP: St James's hospital

GP: Maybe you know nursing colleagues to nursing colleagues

MP: I have some colleagues there in the DSIDC the Dementia Services Information and Development Centre.

GP: I mean say evening times there's the post graduate centre in St James which should be open to hiring out or whatever. There's just a small charge, it's certainly not prohibitive you know. That would be kind of anonymous for people if you like off-site here but convenient and if you're thinking maybe hospitals are good sites or schools. I mean I'm impressed by schools I mean schools turn out in the evenings into all kinds of things going on in schools and quite rightly too there a community facility rather than just chalk and dust and all that.

MP: that's really just the first part so the second part is something that we mentioned in the letter but it's kind of further down the line. It's the feasibility study it's a little bit different in that we would be looking for the practices to recruit 25 patients. I know it's a bigger number than 6 to 8 so that's something you can have a think about. So if it's something that you or maybe other GPs in the practice maybe interested in.

GP: So the original 6 to 8 would be people that we will identify then you would then contact. Ah we'd obviously need to identify you're going to have a refusal (criteria) don't you.

KP: We have the eligibility criteria for patients in midlife so between 40 and 60. Have I think one of the risk factors associated with dementia. They have to have been attending this practice for over a year. And what we would do is we have drafted a letter, you can print on your headed paper and send to out to the patients that you think would be eligible.

GP: That's not how I would do it

MP: we are working with other GPs so what they are doing is either talking to the patients as they come in or phoning them in advance to say is this something that you might be interested in.

GP: yeah sure yeah cold calling or a letter arriving cause's horror

MP: yeah alarming people who would think god am I at risk of this? Why did they choose me?

GP: and then the 6 to 8 right for our point of view we would have to ask more to get that then you don't want to use them again?

MP: we just feel that they would be primed if you like about what is involved. So if they were to go into the control group it doesn't really make sense because they have already seen this information. But we feel it would be wrong not to allow them to have access to the In-MINDD system so we might if they wanted to that they would have access to the

dementia risk score and the online support. But they wouldn't be part of the feasibility study

GP: Right ok because I think otherwise you would have ethical problems

MP: that's what we were concerned about and we didn't want to say to people you can come along but you can't take part later on.

GP: I might bring _____ (name protected) you know _____ who is the intern here. I saw this and I thought ah Ill hand it on to _____ it seems to have come back to me.

Note: GP4 leaves the room

KP: I think St James would be perfect for around here

MP: Yeah

Note: GP4 enters the room with GP5

GP5: Hi how are you?

KP: Hi

MP: Hi

Note Introductions: GP4 makes introductions

GP4: Sorry do you want to just go over that again quickly

KP: Yeah

GP4: Maybe I'll go over it so then you can be sure if I have got it or not

MP: Yes

GP4: so basically this is a study looking at people in midlife 40-60 who might have a risk factor for dementia later in life and who's risk factors would be; diabetes, high blood pressure, hypertension, high cholesterol, depression, ,

MP: obesity, physical inactivity

GP4: and that we would approach the patients when they come in or we would see how they would do that, to see whether they would take part in a focus group 6 to 8 about In-MINDD ok. They would be asked various questions to see what they thought about the questions rather than to give their answers. This is through a view to forming the questionnaire that would be used in a study later on.

GP5: Sure

MP: we have the questionnaire formulated, I suppose it's more about whether this is something they might like to use. Is it acceptable?

GP4: Sure there's probably going to be changes to the questionnaire unless you're very good. I'm not saying that you're not. I think these things do change. That would be the first part. So what we would be doing is looking at people we come across and say would you be interested in and that kind of thing. Now what's in it for them, for these patients, the initial 6 to 8 are they just helping out?

MP: Just helping out

GP4: they would have access to the In-MINDD structures but they wouldn't be part of the study. Because they are tainted by having some prior knowledge and then is that it? That's where we got so far is it?

KP: yes so the next bit is the feasibility study. So the feasibility study will start in July it runs for 3 months.

MP: 6 months

KP: oh sorry 6 months so we're then looking for 20-25 patients from each GP hopefully to try to get to take part to use the online tool. There will be two arms there will be a control arm and an In-MINDD arm we will ask them to use it for 6 months then.

GP4: Would the control arm would they go online? Would they have some kind of eh

MP: they won't for the first six months but at the end of the 6 months they will get there dementia risk score and they will get access to all the supports as well so there's a delay in the time that they will get it

GP4: ok

MP: yeah so we don't want to exclude them totally but we need to have them as a control for that 6 month period

GP5: ok

MP: so the idea is that once the 6 month period is over we say ok were going to do exactly what we did for the other group then.

GP4: How are you going to put that out to patients? Ok I'm the patient and I'm going to be told well you might use this online thing now or it will be in 6 months' time?

MP: yeah how we're going to do it is we make them fully aware of that in the information sheet that we give them and through talking to them and the information that we get. We will also be talking to them at the initial stages and giving them some written information about the various risk factors so if they do feel. Well this is something that I have. They would be aware themselves you know. If someone is obese they will know that and see that might put them at a greater risk of dementia. I suppose one of the things we are trying to see is that if people just get information and the usual care of a GP does that make any difference in comparison to this online support.

GP4: yes I mean because you have already identified to them that they are at risk. And so they might have taken some action.

MP: you know one of the findings might be that people do make changes you know just by knowing having more awareness about this. You know so I guess that's one of the things we are trying to look at in the whole system. But we can't leave them with nothing so they are not left out. But they will not have access to the online system that we are developing.

GP4: Have you seen something that's been produced I think it's being produced by somebody in Trinity its on mental health basically. It's a little video

MP: about the neo program, freedom videos there's a whole range of them

GP4: they cover a lot of this area,

MP: cartoon, they cover a lot of this area

GP4: That's right

MP: it's the Neo program, Sabrina Brennan is the lead.

GP4: I've just seen it I didn't take too much detail out of it.

MP: one of them is a video about lifestyle risk factors and dementia so it might be something we include on our online environment so people can look

GP4: because it's out there and its coming from somewhere nearby so I think they were trying to access local community groups so I think I put them in touch with the F2 centre in Fatima and other community groups you know so just in case that might have been fouling your picture.

MP: it's a little bit different from what we are doing

GP4: Oh I can see that

MP: it is awareness raising is what they are doing as opposed to an online intervention

GP4: ok right so what the practice would be involved in for the first 6 to 8 would just be identifying people giving you the names I presume. And well giving you more than 5 to 8 because there would be a drop-out rate or would you prefer that we just give you 6-8 names and you see what the up take is and we can get you more than when they?

KP: yeah

GP4: rather than, your focus group does that have to be a particular size

MP: well the minimum would be 6 really

GP4: and the maximum

MP: 8

GP5: is that per practice

MP: yeah

GP4: Does it change the dynamics if your focus group is 10

MP: well we could change that, 6 to 8 is the optimum number they say but they do say the optimum number is 8.

GP4: Somebody lays it down somewhere and nobody remembers where

KP: if you have too many more after that it becomes kind of diminishing returns because people because some don't get to talk and others take over.

GP4: sure but there are these authoritative statements, I've had numbers that I first arrived at on the back of an envelope recorded back to me as absolute truths and they were my own numbers. And I know what the origin of my number was and I wouldn't stand over them. And I have had them reflected back to me as absolute truths. Carved in stone you know.

MP: yeah

KP: I think more people won't be a problem as opposed to less.

MP: and if we have too many we can always have 2 focus groups. We're flexible basically.

GP4: yeah sure sure

KP: so during the feasibility study the way it will work is that the patient will input their information with the questionnaire, and when the questionnaire is filled out In-MINDD will tell you how at risk of developing dementia in later life you are. It will produce an action plan of ways to reduce your particular risk factors. So what we need their form the GP, because it's a decision support system is to either look at the plan and ok it or say it's not ok and feedback to us. So let's say the GP looks at the plan and says ok the person needs to do some more activity so we need to know from the GP in case the patient has some hypertensive issues. And we need to do some vigorous activity but in general it's probably going to be yes this is fine. And then the patient can be given their risk score and start to use the online environment and supports to hopefully try to bring down the risk score. So the GP might get a number of plans sent to them, the plans are going to be quite small focusing on one risk factor.

MP: it will be focussing on the areas where they might have a risk so for example if they are obese and physically inactive but they are not a smoker. We won't be addressing smoking or cholesterol there. We will just pick the ones that they are particularly high in and focus on them. And the approach we are going to take is not to try get them to address everything at the one time but to pick something one thing that they think they can make a change in.

GP4: I'm just thinking about diabetes, high cholesterol, blood pressure etc. you know what about family history?

MP: we are collecting information on the family history but because we are trying to focus on the modifiable.

GP4: which you can't alter

MP: Yes because you can't alter it we are not trying to modify it we are just collecting information and asking people in the questionnaire do you have a family history of it. So one of the things we have been kind of grappling with the risk score, we have been calling it a dementia risk score but we are not quite sure if that is the correct term to use to give to patients. We have come up with a number of different versions. Because there's other non-modifiable risk factors associated with genetics like age and genetics. It might not be the right. So we are trying to grapple.

Note: GP is given hand-out with alternative names for dementia risk score

GP5: I like the brain health score

GP4: that's the one I like its positive. Brain health score, brain healthy lifestyle score either of those.

MP: our colleagues in Maastricht like the whole idea of cognitive but then we weren't sure if everybody would understand what we mean by cognitive.

GP4: we would have difficulty conveying that, brain health absolutely or brain healthy lifestyle whichever one comes.

MP: We also thought In-MINDD score but again you need to explain.

GP4: what do you mean by that, the other 2 are self-explanatory if you like.

MP: and it is a positive message.

GP4: yes this is what you can do with yourself

KP: should we go through the profiler

MP: do you want me to show you our questionnaire which we have developed?

GP4: Yes yes

MP: it's quite lengthy but I think you can skip through some of it. There's one part of it that isn't there but it's a cognitive activity questionnaire. That will be looking at people's level of education.

GP4: So the first are all demographics. Mood ok.

MP: that's the CES-D you may be familiar with.

GP4: No

MP: It's a 20 item questionnaire that asks people about different aspects of their mood over the past week. It's quite straight forward its really widely used there's kind of a cut-off point.

GP4: Ok.

Reads through hand-out

GP4: they might come back to us for some of these you know is that allowed?

MP: yes what we were planning to do and we will explore this in the focus groups is for us to give the GP sheet and they fill out cholesterol levels and blood pressure levels. Then they give that to the patient. And then the patient inputs it themselves into the profiler. So they will have the correct information rather than not knowing it but we won't ask you to take cholesterol readings if they haven't been done already. So we are not asking for any additional tests.

GP4: they look alright yes. For household activities every male in this area, never.

MP: (laughs)

GP4: and even if they did they would never admit to it.

MP: then maybe that's a recommendation we will have for the men.

GP4: you don't see too many guys knitting either. (laugh)

GP4: they seem alright just ah I'm not so sure what household activities will tell you.

MP: well it's a cognitive activity score. It's really looking at, research is showing that people who engage in cognitively stimulating activities and household activities for their physical health as well is important. So it's just a way of trying to assess that which isn't easy to assess but that's the best instrument that we have found. So we are trying to go with that.

GP4: ye sure, it does look alright ye.

MP: so do you want to say a little bit about the support environment

KP: so basically patients' em they have their questionnaire filled out, they have their action plan and that leads them onto a supportive environment. Which gives them information on their particular risk factors and we are looking into ways of using forum type supports where patients that have the same risk factor they are maybe both trying to stop smoking. They can talk to other people that are using the system about that.

GP4: peer support

KP: Peer support yes and a FAQ type where patients can ask the experts questions. We have experts in Ireland and Scotland to answer these questions. After a while these will be put into an FAQ.

GP4: There is Glasgow, Maastricht, and Nice.

GP5: oh right

MP: we hope that people will go in and do their own language. What we plan to do is each country will submit their FAQs so that we can populate our own countries language with it as well. We can see the similarities and differences with it as well. Then there will be information about each of the risk factors and links to existing websites and national websites we are trying to find ones that match at the moment. People will be able to click on those and get access to get active Ireland. You know the health promotion websites that are available and the kind of activities I their area that type of thing. And then some personalized supports where they will get some prompts or questions about which ones you have selected, how have you been doing with that? As they go along.

KP: and there would be weekly updates or monthly updates depending on how it works were trying to get them to keep using In-MINDD.

GP4: I think you would find a good number of our patients wouldn't use the internet.

MP: So that might be an issue

GP4: it could be an issue, it could be. So maybe just see what the local services are like the F2 centre there which has got a lot of activities there you know the idea of men's sheds and things like that and there's dancing. I think you would have to because otherwise you would be cutting them off.

MP: we were hoping to get very localized supports for people in each area but it's how to do that for all of the areas throughout the country is the difficulty?

GP4: so where are you getting your docs from at the moment?

MP: at the moment we have 4 GPs who are interested and we have others who have expressed an interest. There all in Dublin and one in Cork who might come back on-board.

GP4: So where are they in Dublin?

KP: Cabra, Whitworth, Marino, Griffith Avenue. So far we have two practices where the doc says everyone has access to IT and two where most people don't have access.

GP5: is that Dr _____'s practice

MP: No, with confidentiality I don't know if I can discuss it

GP4: I could guess but I'm too polite

MP: maybe we can ask the other GP if they are happy to share. It may be a nice network for them to have.

Time: 30.00

GP4: one way of getting that is to look at a primary care team and there should be a primary care team manager to give you the local community facilities.

MP: so link the patient into the primary care team

GP4: or you get the information from the primary care team manager for them (patient)

MP: That's a good suggestion

GP4: you know the idea of men's sheds, men won't go to a knitting class, they're not going to that but they will do stuff and then they finally talk to each other. But it's a slower process. You know men come out of their shells very very slowly. Whereas, women talk and socialize mostly very easily. With us it's a slower process to get them out.

MP: that could be explored more in the focus groups. We can say is this enough to have it online?

GP4: Do you want mix; do you want four women, four men?

MP: that would be good if you can achieve that.

KP: and also a mix of risk factors but we can only look at risk factors that clinicians take in themselves.

GP4: the ones we expect you may not know about are the physical activity and the cognitive activity

MP: the others we reckon you might have a fair idea about

GP4: A quick eyeball would tell you about the physical activity

MP: the other thing we were hoping for in the feasibility study is that they may be able to come in and talk to the GP about it. If they felt a need to do that. Is that something that you would be open to or is that problematic in anyway?

GP4: right it depends on how many there were.

MP: we are talking about 25 half of which will be in the control group.

GP4: I think maybe you say when next visiting your GP rather than 25 more consultations you know and there might be an expectation then that there is not a charge. So I would say when next visiting your GP. Because by and large we don't sit idly here, we move all the time. We have some present problems with the minister and his under 6's deciding that he wants us to do this that and the other. Where? How? Who? What? And he's saying all this without evidence to say that what we are doing at the moment isn't good.

MP: One of our other GPs said that she could perhaps talk to her patients over the phone. Have a quick telephone conversation. Is that something that may be workable?

GP4: Yes. Ok what we don't want to do is open ourselves up to unnecessary or a lot of work while trying to assist the thing.

MP: I understand. Could we just ask you before we finish what your current practice is in relation to people you think that, or is it something that is discussed with patients that they may have a risk of dementia in the future? Or is that ever addressed with patients?

GP4: Probably no no at that level. Probably you have a risk of your overweight let's do something about that, you're smoking let's do something about that. You're whatever else it is or you're blood sugar, we do run the diabetes clinic here, we run 24 hour BP monitors so we try to look at people with hypertension. So we are active in these areas but they wouldn't be with a view to

MP: More to do with heart attacks and stroke

GP4: it would be more to do with general overall health and wellbeing rather than specifically mention dementia or failing brain or whatever you want.

MP: and do you think that's a conversation that could be opened up with patients through this system or is it something you think is necessary.

GP4: well ye you could certainly I might also start to use that as part of the thing. You would be at risk of maybe you know Alzheimer's or something like that. But I prefer to go on the positive rather than the negative. You're preserving function including brain function that would be the better message you know.

MP: Right is there anything else Kevin?

KP: em

MP: In terms of the advice you give to people in terms of obesity would you link them into programs that are currently available.

GP: I'd be pushing the 5 and 2 diet. You know this 5 and 2 diet Michael Mosley OK. They have operation transformation up there in the F2 centre so there are things there. The dieticians do not want to see people who are overweight unless they have some other problem. Because they have pretty good evidence that sending people who are overweight to dieticians doesn't work. So you know it has to be for another reason. So I think we come at it from a more positive thing.

KP: would you ever put your patients onto specific websites like getactiveireland.ie or any of those types of things.

GP4: I haven't really but maybe we need some education on some of those things as well.

MP: when we develop this support system is that something that you would like access to as well

GP4: Do you mean because of my age, they're being ageist now.

MP: I mean as a way to support your patients

GP4: Yes I'm interested my father had Alzheimer's so, I'm quite aware that I am beyond your age group. I would be actively aware of the limits and what you can do to help your own brain health. So yes of course anything that can help. I think our next generation of patients are going to be internet savvy. But we have a group at the moment who ain't. And who would be a lot younger than I am who are not. Which is quite disappointing.

KP: that 40-60 age group?

GP4: Yeah there would be a good lot of those there who, it's the new marker. It used to be literacy, its now internet literacy.

GP5: How do you tackle that problem in areas like this?

MP: Well that's something that we will have to look at as well but you know one of the things we will try to do is make all of the language very plain. Very plain language and easy for people to understand no difficult terms. So we are conscious of that.

GP4: So this is all web based is it.

KP: Its all web based. So from the outset you are always going to be missing a segment.

MP: I think it's good for us to talk to the focus groups to get insight into

GP4: yes because that's quite discriminating isn't it

KP: It's an online tool

GP4: I don't mean purposefully but it is.

KP: Yes it is

GP4: what's the old story about one of the first poll that they did in American election? An according to such and such poll a body was going to be president. And they were wrong because there was only a small percentage of the population had telephones.

MP: So we will have to work with the group to find that out. So in completing the profiler we are going to be present if they need our help to do it. So I mean we can get over that part of it but in terms of the online supports, that's tricky and it maybe and extra finding from the study that maybe it's not workable if you're going to exclude a whole cohort of people who don't have access to it. SO we may have to find other ways around it.

GP4: or you find a different way around it. Say people will have to be employed in the F2 centre to help people go through. Actually have a mentor to help them through the thing.

MP: these are the findings that we will actually get from the study that will help us address these issues in the future. We don't see this as being the end product if you like. It's part of a learning exercise. About a wider health promotion initiative

GP4: Sure sure,. And it really does depend on where you go. If you go to schools and colleges everybody's internet savvy. But you come out and there is a big group of people who aren't

MP: that will make us rethink things. Which is an important finding in itself. So that's why we are glad to get people form quite different areas.

GP4: I think there was a survey out recently and I think we are low down on computer access or internet access in schools compared to other countries.

MP: I think there is an assumption there that everyone has access to it. The message is getting to those who have access but not those who don't. It will be interesting to talk to those people and find out what they have to say.

MP: So is there anything else you would like to ask us.

GP4: No

GP5: What's your aim in terms of numbers?

MP: For this part of it we are meeting with four GPs and we are getting a focus group from each of them. So that will be 6-8 in each practice. For the feasibility study we will have a bigger number of GP practices. Six at minimum and in each practice there would be 25 patients. But we can come back and talk about the feasibility study again and you can tell us if you want to go ahead with that or not. We'd be delighted to have you on board obviously.

GP4: Ok I think we would certainly be on board. Ok and you say that we would be recognised as authors on any articles coming from this. I think that's important because we are not just there to sort data for other people to use.

MP: yes

GP4:

MP we also have an emailing list would you be interested in having your email address on that so that we can keep you up to date with any progress in relation to the

GP4: You have got my email?

MP: No

GP4: oh right so it's ███████████████████████

KP: is the consent form filled out?

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GP4: Oh right. So right you have just recorded me now. Is that part of the study somehow?

KP: Basically what will happen there is they will all go into files that are password encrypted. I'll transcribe them myself, they'll be anonomized and all names and practice information will be taken away from them.

GP4: Sorry to what end?

KP: to go through the transcriptions and look at the themes. And the information then feeds back to the development team. So you're looking for the main themes form here, form the GPs in Maastricht and Glasgow.

MP: So one of the main themes from here that we would have been already aware of was the cost to the patient of attending the GP. Which they don't have that issue in other countries because it's free at the point of use. So even the design of the whole intervention has changed because of those issues. We are trying to make it similar across the four countries.

GP4: Are they going to have be GMS patients or?

KP: well in Scotland they will mostly be NHS patients, here no no no we don't want to limit it GMS patients. We want everyone but it just means we have to take account that there is a cost borne by GPs or by the patient depending by the way we organise the intervention. We just have to take account of that and the other countries just have to take account as well because of the difference between our system and the system of the different countries.so there the kind of issues that we want to look at because we want to see how this could be used in everyday practice in GP surgeries after the project is finsished.so we have to take account of the themes that are emerging. So it's with a view to informing the design and the development of the system.

GP4: So this is your PhD is it?

KP: Yes my PhD is all around the co-design phase, the phase where we are developing the system the research and development. So my baby is the interviews the focus groups . Feeding into the IT group that are coming up with the system. Also if there are further focus groups when the feasibility trial is finished, we might look into having some focus groups with the people that use the system for 6 months.

MP: Originally we had the GP inputting the information into the system but that didn't make sense. We had feedback form other GPs saying that it wouldn't work. So now we have changed it so the Patient enters all the information.

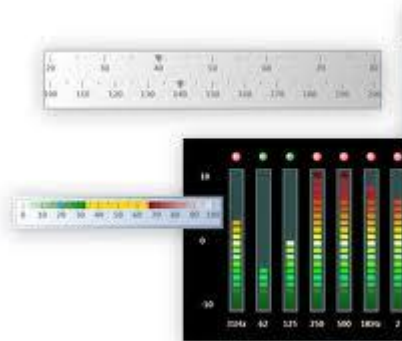GP4: The patient is then taking responsibility for it. It's buy in.

KP: That's what it's all about.

Finishing remarks. Goodbye1

Appendix P: <u>GP Interview Abridged Transcripts arranged by Theme</u>

GP Interview 1

Theme	Explanation	Quotes	
General Knowledge of, attitudes to and current practice regarding dementia deterrence			
Motivation	People who are interested in their own health are more easily motivated compared to people who are less health conscious.	"Patients who you can probably motivate better for heart attack and stroke are probably patients who are interested in things and might actually be less likely to get dementia anyway because of just keeping more in tune and involved with everything that is going on around them." "Sometimes you get questions from the worried well who may have forgotten some things. People who ask are usually the proactive healthy people looking to protect their health. You wonder if you are getting a self-selected population coming forward to prevent dementia who are generally the clean living healthy people interested their own health, current affairs playing bridge and that kind of thing."	"I could see some people seeing some of the risk factors, an orange light come on the dashboard and doing something about it."
Risk Factor Awareness	Awareness of modifiable risk factors for dementia	"Patient's understand their heart being protected more so than their brain being protected."	
Cognitive Activity	How cognitively active a patient is	"I would say I probably wouldn't have much of their cognitive skills at that age when they are not sticking out as a really healthy 80 year"	
Identification and Recruitment of potential patients - Processes			
GP Attitude to recruitment		"Patients are always happy/ interested to get involved. Patients never say no"	
Recruitment	Focus Group Recruitment	"We use standard coding procedures for all our diagnoses in work so we have lists of people with hypertension, high blood pressure, renal disease, hypercalcaemia, cardiovascular disease etc. It would be no problem recruiting people with one or multiple illnesses."	Yes we can print the letter (DCU focus group recruitment letter) on our own headed paper and post it out ourselves.
Profiler Inputs/Outputs			
Clinical inputs	Profiler questions	"If patients get in contact before they come visit it is really easy for us to. There is a basic results bar we can click on it and print off in excel. Their cholesterol, blood pressure, height, weight, BMI"	
Depression	Profiler questions	If there was someone with depression coming in with high blood pressure or obese we would still be addressing it. We wouldn't ignore it just because they have depression. The big thing is stigma in mental health and not treating their underlying physical causes because they happen to have a psychiatric diagnosis."	
Renal Disease	Profiler questions	"14 (Renal disease) is one we are becoming a lot more aware of. Its only really exploded into our consciousness in 2007 when they changed the UK GP contract to start recognizing chronic renal impairment.	

Attitude to Profiler questions	Profiler questions	"This is all very do-able."	
Risk Score, Action Plan and Supportive Environment Topics			
Risk Score Example		"That is the one that would really appeal to me. Example 2."	"I think a headline score and maybe a histogram example 4 for different factors."
Website recommendations		patient.co.uk	
Research Process Issues			
GP Charges	GP will forego some charges	"I was sort of thinking about it if it just generates one or two visits it's not much of a problem. There only going to be my patients at work that will be coming to see me so I will say to them that there won't be a charge for this."	
Feasibility Study		"That shouldn't be too much of a problem, we can pull electronic lists and we will know who is not too busy and agreeable."	

GP Interview 2

THEME	EXPLANATION	QUOTES
General Knowledge of, attitudes to and current practice regarding dementia deterrence
Attitude towards Dementia Risk Deterrence	GP does not try to target dementia risk factors specifically. However with the crossover with cardiovascular and cancer risk factors similar clinical risk factors are targets.	"Ideally you don't want to raise a hair if you can't do something about it" "If someone came in and asked about it I might bring it up and often that comes up in families where there is a history of dementia in the family so they are saying what can I do?" "In that I would be encouraging people to be in clubs or taking part socially or doing things that kept them active mentally. Whether that is bridge or crosswords or Sudoku's or just talking to people you know. But we are not doing that in any systematic way." "No I don't think that I would talk to patients about it. I talk to patients a lot about lifestyle stuff but it is mostly cancer risk and cardiac risk that people would be conscious of. So a lot of things actually cut across."
Specific Dementia Risk prevention Services		KP: "So no targeted specific services?" GP: "No"
Identification and Recruitment of potential patients - Processes
Recruitment	Patients with risk factors will be easy to recruit.	"No problem again we can find hypertensives from our system or we can take patients opportunistically as they present. Hypertensives and diabetics are coming in regularly."
Health Conscious Self-Selected Sample more likely to participate	Enthusiastic health conscious patients will participate. Other patients will miss out.	"If you take people opportunistically you obviously have that bias of taking people who are interested in their condition and turning up. So you'll miss the people who are uninterested." "We had a similar study of patient led interventions in diabetes about 8 or 9 years ago. Again it was the enthusiasts who showed up and volunteered to be involved and they are not your average."
Profiler Content Questions
Cognitive Activity		"apart from very basic stuff I don't think I don't have any easy check list in my head that I go through with people or apart from general stuff of encouraging people to join whatever local societies."
Cholesterol		"Cholesterol depends on the patient, they have to ring make an appointment go have the cholesterol taken we would have quite a good coverage of that for those who are attending." "The patient would say I have a cholesterol problem but they wouldn't be able to say if it is 5.5 or 9.5."
Clinical Information		"So of the people who are attending pretty much everyone will have blood pressure, we're not as good in terms of height and BMI." "Again we can do it either way we can pick people who have those if there is information missing we can organise to get it done."
Renal/ Kidney Function		"I'm not really aware that is a risk factor for dementia." "I couldn't claim that I am doing this to prevent dementia I am doing this because I don't want your kidneys to fail or I don't want you to have a heart attack or a stroke because you are at a higher risk of those."

Physical Activity		"While I would have an approach to physical activity I would be doing that in relation to obesity management or diabetes or cardiovascular disease."
Communication with patients		"We don't email and we don't text. Phone calls letters or consultations yeah."
GP comments on the In-MINDD Profiler hand-outs		
Profiler	In relation to education questions	" we would have a lot of people of low educational attainment and they might not even fully get what you mean there."
Serving sizes	Diet questions	" when I'm talking to people about dinner quantities I talk about dinner plates."
Attitude to profiler	GP attitude	"I don't see that there is anything insurmountable in it."
Risk Score, Action Plan and Supportive Environment Topics		
Action Plan Example Pictures	Which types of images to use	"The cardiovascular risk charts are something that pretty much every GP is familiar with." "It's the European guidelines on cardiac risk."
Engaging Patients		"How do you keep people engaged? When people fill out the thing and get a plan back that tells me I really should do this and this and say Whoa! not going to open that page again."
App Suggestions	Suggested link for supportive environment	"Run keeper does that to you. If you haven't been running for a month it says what are you at?"
Smoking		The message they will get here is smoking is 10 times more important than anything else so if you are going to do anything to pick smoking first and we would run through that with them.
Patient Attitude to Preventative Health		"Generally people are more interested in what you can do for me unfortunately. So they want us to fix them. So then you're into cholesterol management and blood pressure management."
Peer Support	Supportive environment	"I think that again there is the enthusiast's and people who really want to try do that sort of stuff so it's not everyone. There would certainly be a subgroup but I'd be guessing it's not more than 20% of people."
Services for Patients		"There is lots of stuff you see around like hotlines and you see The Mater (*hospital*) has a smoking cessation set up there." "We give them diet sheets here, if they have diabetes or are over 65 they can get access to the community dieticians. It's a very variable thing and depends on which primary care team are you are in and whether there is a dietician in or not."
Motivating Patients		That's always the challenge you want to make people mildly anxious so they will change but you don't want to push some people who are already highly anxious with red danger signs. What do you do then? "Again there'll be a range some people you'll be trying to beat off because they will be filling out here assessment every week or people won't go near it. My experience of lifestyle interventions is that it's a minority interest but it makes a big difference if that minority is 20% or

		30 %."
Obesity		"We send most people to weight watchers to me that's the best."
	Research Process Issues	
Access to IT:	GP has concerns about IT literacy amongst patients	"Our practise is heavily GMS so we have significant literacy problems significant lack of access. A good third or so of people would say I can't use computers, would have difficulty navigating. So it's higher than you might realize. I sent a lot of people to citizens advice or local partnership offices or the Dublin city libraries will often help people if they don't have a computer themselves or they need access. It's a motivation thing sometimes people just feel embarrassed, you know everyone knows how to use computers. Even mobile phones a lot of people would still be using a basic phone as they haven't got themselves over that hump."
		"We meet lots of people every day who never read a paper, don't do anything online."
		"There is a huge social gradient. Income wise and education wise. If you're talking about people under the age of 35 there is no issue. If you're talking about 40-60 cohort there will be a significant number who never had to use computers and have missed the boat."
Recruiting Approach		"I'd probably just do that face to face it works better I think."
Irish System Private and Public (GMS) patients		"Well it's a problem in both systems obviously there is a patient barrier in terms of bringing patients back because they will have to pay."
		"There is no preventive pay within the GMS at all. There is nothing in the scheme (for prevention) it presumes the patient will come to you if they are ill. There is absolutely no funding for prevention except for the flu vaccine."

GP Interview 3

THEME	EXPLANATION	QUOTES
General Knowledge of, attitudes to and current practice regarding dementia deterrence		
Attitude towards Dementia Risk Deterrence	GP does not want to give the patient another problem. GP	"Certainly I would never say to them the best way not to get dementia when you get older. That wouldn't be a conversation I would have. But I would encourage." "Ye it's like you're telling them that you could have a heart attack or you could have a stroke and the worst thing if you have a stroke is that you might not die. So all that kind of stuff you are already bombarding them and you say you are going to become demented too. It is not necessarily something that you want to do." it's probably not something that is promoted to us that much. What am I 15 years in general practice, it wouldn't have been something we did a huge amount about." "yeah at the time it was either you had Alzheimer's or you were just a bit forgetful as you got older. I suppose all the vascular dementia stuff has come out more recently." "I'm probably not very good, it's more when you have somebody in who I am worried may be showing symptoms of dementia. Then I would be looking at it retrospectively perhaps more than actively."
Inadvertently treating risk factors		"the risk factors that you have shown there I would be treating those as I go along so inadvertently doing it without realizing that I am."
Cardiovascular risk over dementia risk	GP would talk to patients about cardiovascular risk or cancer risk not dementia risk.	"Probably not their risk of dementia I would be more likely to talk to them about their cardiovascular risk rather than actually their risk of dementia. I would try to get them, probably cognitively active no but I would try to get them physically active. Try to lose weight, do all of those kinds of things.
Depression		"More so on the depression I would say to get out there in groups, without thinking about it without formally."
Vascular Dementia		"yeah at the time it was either you had Alzheimer's or you were just a bit forgetful as you got older. I suppose all the vascular dementia stuff has come out more recently."
Identification and Recruitment of potential patients - Processes		
Recruitment		"There are 500 patients in that age group registered. Now how many of those patients are active or not I don't know. They tend to be of an age group particularly the 40-50 year olds who probably aren't in that often. The women have stopped having their children. For the 50-60 age group you would have a better idea but for that age group you might not. So while there is 500 patients that might actually be a 100 (active)." "Yes we should do, If we have been good enough at putting the information into the system. I can certainly do a trawl of who is on anti-cholesterol medication, or anti-hypertensives, or looking at their past medical history and things like that yes it should." "ye but I would be more likely to ring them actually. Letters tend not to work I would be more likely to ring and tell them I am going to send you out a letter. That would be more likely to do it."
Posters in waiting rooms		"Ye that would be fine."

Face to face recruitment /Practice website		"Ye that would be one way of doing it. The other thing is we have the website. I could always put it up on the news page. I'm not sure how many people actually look at it."

<table>
<tr><td colspan="3" align="center">Profiler Content Questions</td></tr>
<tr><td>Cognitive Activity & Physical Activity</td><td></td><td>"Some I might just because I live I the area, I might see them out and about and I'd know it from that point of view. It wouldn't be necessarily stuff we have sat down and recorded with charts and that kind of stuff."</td></tr>
<tr><td>Renal/ Kidney Function</td><td></td><td>"Some new guidelines have come out to say we are over diagnosing chronic kidney disease. We are probably putting people into clinics that don't need to be there. So I said I'm not going to do that. But ye it would be something that I am aware off yeah."</td></tr>
<tr><td>Depression</td><td></td><td>"If it's a mild depression that wouldn't be a problem."</td></tr>
<tr><td rowspan="5">Knowledge of Family Medical History –</td><td rowspan="5">Individuals may not know these things</td><td>"the family history of vascular dementia you are going to find that hard because they won't necessarily know."</td></tr>
<tr><td>"oh ye she had dementia but I don't know which type of dementia it was we were never really told half the time you would be amazed how many people don't know."</td></tr>
<tr><td>"I'd put irregular heart rate in there in terms of heart disease and cardiovascular. They might only know that they have an irregular heartbeat but they don't have any heart disease."</td></tr>
<tr><td>"See here where it says chronic kidney disease or abnormal kidney function results. If they have been told that then you should be able to get that result. You might not tell someone they have kidney disease you might say the kidney function was a little bit off we should check it."</td></tr>
<tr><td>"if I am reading it I will not necessarily say to my patients you have chronic kidney disease. So they might say no to that but might have it."</td></tr>
<tr><td>Attitude to profiler</td><td></td><td>" it seems fairly straight forward"</td></tr>
<tr><td colspan="3" align="center">Risk Score, Action Plan and Supportive Environment Topics</td></tr>
<tr><td rowspan="2">Action Plan Example Pictures</td><td rowspan="2"></td><td>"I think guys would like those they are very male. That's my first impression they are all things from cars. You know I don't know how you could do it any better but that's what really strikes me. It's very male."</td></tr>
<tr><td>"Something like a traffic light kind of system. Or there not so bad if it was more like a kind of a pie chart"</td></tr>
<tr><td rowspan="2">App Suggestions</td><td rowspan="2"></td><td>" that couch to 5k they have great podcasts that you download onto your phone. It tells you how to stand and how to hold yourself and all that kind of stuff. They're great."</td></tr>
<tr><td>"myfitnesspal, patient.co.uk you can register with them they are very good. They would tend to be the ones I use most often just in terms of getting up and out. I think they (In-MINDD users) would find them quite useful."</td></tr>
<tr><td>Blood Pressure</td><td></td><td>"for blood pressure, they all tend to come together, but for blood pressure I would tend to send them to a dietician to check their salt intake and diet and that kind of stuff and to get out and be physically active. You know similar things, a lot of it would be similar to diabetes, weight</td></tr>
</table>

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		management, being physically active, looking at their diet again."
Diabetes	About the X-pert program	http://www.hse.ie/eng/services/list/2/PrimaryCare/pcteams/dublinsouthpcts/dunlaoghaireglasthulepct/xpertdiabetes.html "it's quite a good (program) that's the email if you want of the girl who runs it there. debbie.grealish@hse.ie" they run it twice a year/3 times a year in different parts of the city. It's like a group kind of a thing they talk about healthy eating, activity, how to manage your diabetes all that kind of stuff" "and they self-refer to it so they can just ring and sign themselves up for it."
Services for Patients	HSE run services	" you see some things are available in some areas and not in others. I haven't heard of it usually if it's available. The HSE do run smoking cessation classes and stuff like that. A similar kind of thing and stress management they do a stress management thing as well they have some reasonable initiatives dare I say that out loud."
Depression		"With depression not specific kind of stuff book more so self-help books more than necessarily online tools, tell them to go down to the library. There's books down there I would tend to recommend. There's a kind of CBT that you can do online and stuff like that but you know for those who can't necessarily afford see a councillor."
Obesity		"Obesity yes myfitnesspal because you can do a calorie counter and things like that on it if they have it. Weightwatchers and slimming world and they have support groups to try and help. We have a reasonably good dietician service. We refer them to a dietician sometimes.
Research Process Issues		
Access to IT:		"Most of them certainly in the age group you are talking about yes the vast majority would. There would be very few any more that don't. Maybe as you get to the sixty they mightn't but certainly any that are at work or do anything like that would. Most of them have smart phones. We'd have a reasonably high level of education in the area."
GP want co-design individuals allowed to use In-MINDD		"ok and the initial 6 or 8 are they allowed to follow on or do you exclude those" " you kind of have to, you know your great thanks for helping us off you go"
Patient visits as a result of In-MINDD		"Well its fine if it's part of another visit. But if they specifically come in just for that? If it's part of another visit you don't charge them any extra. But you would charge if it was to talk just about this. But you could do it over the phone I suppose. That would be fine. But if they wanted to come in there could be charge." "Absolutely but it's a consideration because people are giving their time to take part in the study they would feel so why should they incur a cost to take part in the study."

THEME	EXPLANATION	QUOTES
General Knowledge of, attitudes to and current practice regarding dementia deterrence		
Attitude towards Dementia Risk Deterrence		"Probably no no at that level. Probably you have a risk of your overweight let's do something about that, you're smoking let's do something about that. You're whatever else it is or you're blood sugar, we do run the diabetes clinic here, we run 24 hour BP monitors so we try to look at people with hypertension. So we are active in these areas but they wouldn't be with a view to" "it would be more to do with general overall health and wellbeing rather than specifically mention dementia or failing brain or whatever you want." "well ye you could certainly I might also start to use that as part of the thing. You would be at risk of maybe you know Alzheimer's or something like that. But I prefer to go on the positive rather than the negative. You're preserving function including brain function that would be the better message you know."
Attitude to Research		"Ok I think we would certainly be on board. Ok and you say that we would be recognised as authors on any articles coming from this. I think that's important because we are not just there to sort data for other people to use."
Identification and Recruitment of potential patients - Processes		
Recruitment		"yeah sure yeah cold calling or a letter arriving cause's horror"
Primary Care Team		"GP4: one way of getting that is to look at a primary care team and there should be a primary care team manager to give you the local community facilities. MP: so link the patient into the primary care team GP4: or you get the information from the primary care team manager for them (patient) MP: That's a good suggestion"
Attrition Rate		"and then the 6 to 8 right for our point of view we would have to ask more to get that then you don't want to use them again?"
Focus Group Location		"I mean say evening times there's the post graduate centre in St James which should be open to hiring out or whatever. There's just a small charge, it's certainly not prohibitive you know. That would be kind of anonymous for people if you like off-site here but convenient and if you're thinking maybe hospitals are good sites or schools. I mean I'm impressed by schools I mean schools turn out in the evenings into all kinds of things going on in schools and quite rightly too there a community facility rather than just chalk and dust and all that."
Profiler Inputs/Outputs		
Clinical Inputs		they might come back to us for some of these you know is that allowed?
Attitude to profiler	Positive attitude talking about buy-in or engagement	"The patient is then taking responsibility for it. Its buy in."
Risk Score, Action Plan and Supportive Environment Topics		
Action Plan Example Names		GP5: I like the brain health score GP4: that's the one I like its positive. Brain health score, brain healthy lifestyle score either of those.
App Suggestions	Neo Program	"Have you seen something that's been produced I think it's being produced by somebody in Trinity it's on mental health basically. It's a little video"

Services for Patients		"you know the idea of men's sheds, men won't go to a knitting class, they're not going to that but they will do stuff and then they finally talk to each other. But it's a slower process. You know men come out of their shells very very slowly. Whereas, women talk and socialize mostly very easily. With us it's a slower process to get them out."
Obesity		I'd be pushing the 5 and 2 diet. You know this 5 and 2 diet Michael Mosley OK. They have operation transformation up there in the F2 centre so there are things there. The dieticians do not want to see people who are overweight unless they have some other problem. Because they have pretty good evidence that sending people who are overweight to dieticians doesn't work. So you know it has to be for another reason. So I think we come at it from a more positive thing.
Research Process Issues		
Access to IT:		"I think you would find a good number of our patients wouldn't use the internet. " "it could be an issue, it could be. So maybe just see what the local services are like the F2 centre there which has got a lot of activities there you know the idea of men's sheds and things like that and there's dancing. I think you would have to because otherwise you would be cutting them off." "I think our next generation of patients are going to be internet savvy. But we have a group at the moment who ain't. And who would be a lot younger than I am who are not. Which is quite disappointing." "About the 40-60 age group: "Yeah there would be a good lot of those there who, it's the new marker. It used to be literacy, its now internet literacy" "yes because that's quite discriminating isn't it" "I don't mean purposefully but it is." "or you find a different way around it. Say people will have to be employed in the F2 centre to help people go through. Actually have a mentor to help them through the thing."
GP want co-design individuals allowed to use In-MINDD		" Right ok because I think otherwise you would have ethical problems"
Patient visits as a result of In-MINDD		"I think maybe you say when next visiting your GP rather than 25 more consultations you know and there might be an expectation then that there is not a charge. So I would say when next visiting your GP. Because by and large we don't sit idly here, we move all the time." "Yes. Ok what we don't want to do is open ourselves up to unnecessary or a lot of work while trying to assist the thing."

GP Interview 4

Appendix Q: <u>Service User Focus Groups Abridged Transcripts</u>

Co-design Patient Focus Group 1 & 2 – Third Round Analysis

Overview

 Focus Group one was attended by 5 (2 male, 3 female) individuals aged between 45 and 60. Some of the participants attended a cardiac rehabilitation program. Two of the participants had undergone surgery for stents to treat heart conditions in recent years and one was a diabetic. Focus group two consisted of three people, 2 male and one female. One participant was a diabetic. Both focus groups were attended by the researcher and a research assistant. For the purpose of this analysis information will be organized thematically giving findings from the two focus groups conducted.

<u>Leisure activities</u>

 The types of physical activity reported by participants varied from walking to taking part in triathlons (sea swimming, jogging, and cycling), Kayaking (sea, river) and attending a gym. Some participants reported previous involvement with sports or exercise such as walking and indicated a wish to return to more regular exercise. Playing musical instruments such as guitar/banjo was reported as a hobby or leisure activity. Other hobbies included crafts such as patch work and reading.

Dementia Knowledge

 All participants indicated a knowledge of dementia from having close family members, e.g. mother, mother-in–law, aunts, who had been diagnosed with dementia. Participants were unsure about the difference between Alzheimer's disease and Dementia. This question was subsequently included in the FAQ page of the support environment. Participants talked about relatives with dementia having been taken advantage of by criminals (e.g. being accompanied to a bank to withdraw money) and of a relative with dementia leaving the house and getting lost.

Participants commented that much of the information on dementia that they would come across would be from television documentaries. Another participant commented that dementia seemed to be getting more common: "*I would know that it's getting more common*". This question was subsequently included in the FAQ page of the support environment

Risk and Protective factors for Dementia

<u>Cognitive Activity</u>

Participants indicated awareness of the link between cognitive activity and its protective role in relation to dementia. Cognitive activity was likened to exercising the brain like a muscle. A participant talked about his mother with dementia doing crosswords and puzzles as a method of trying to slow the progression of dementia. Participants reported reading, playing chess, cards, scrabble as activities that could enhance brain health. This indicated an awareness of cognitive activity as a protective factor: "*I love scrabble and play on an Ipad against the computer. So it's all about speed and I'm aware that by doing that you're stimulating your mind but I love it anyway. Hopefully it'll keep something at bay*"

Blood Pressure & Cholesterol

Participants wanted to know if managing cholesterol or blood pressure with medication could help to decreasing risk of disease in other areas such as heart disease: *"I have blood pressure and cholesterol issues so what if you are on medication for those, is that controlling it?"* This had implications for the content of the material in the online support environment, for participants on medication to manage cholesterol or blood pressure. Some participants would know that they had high cholesterol but not their specific cholesterol details.

Heart Conditions:

There was little awareness prior to the focus group that a heart condition could impact cognitive health in later life. The following quote indicates a low awareness among participants of heart disease as a risk factor: "*I didn't realize that because I have a heart condition that I am more at risk*".

Following the focus group there was some positivity that by managing a heart condition a potential positive impact on future dementia risk and brain health: *"I feel lucky that I found out I had a heart condition. I think that if I am managing my heart condition I am probably managing the same risk factors for dementia. I think that should be emphasized that positivity that if you are managing your heart condition you are also bringing down your dementia risk."*

Alcohol Consumption

One participant described his mother as drinking heavily for 3 or 4 years in midlife and stopping and later suffering from dementia. The participant suspected that this bout of alcoholism had contributed to dementia. This indicated some awareness of the link between mid-life alcohol consumption and later life dementia.

Genetics

Participants asked about the role of genetics and queried if one has none of the risk factors associated with dementia can one still get dementia. The role of genetics is now addressed in the FAQ section of the support environment.

Disease risk prediction software:

Clinical risk factors such as BMI, Blood pressure, cholesterol, smoking contribute towards a number different diseases or disorders. Programs such as Framingham health collect information on a number of risk factors to give a score for the likelihood of a heart attack in the next ten years. Some GPs thought that one system like this was enough. However the view of the In-MINDD project is that by producing algorithms that give a risk profile for major diseases such as Dementia, eventually other algorithms will be produced to cover more of the major diseases. Eventually heart attack, stroke, cancers, dementia could be screened for using one tool that uses all the available algorithms instead of a number of tools for each algorithm.

Introduction Video.

The introductory video was reported by participants to be clear and concise. However, participants did raise some issues. The three dementia risk factors that can be managed (at least partially) through lifestyle (i.e. diabetes, heart disease and CKD) were referred to in the video as non-modifiable risk factors, and the participants highlighted the difference between these and those that are truly modifiable. The differentiation between modifiable and less dynamic risk factors is an issue that the In-MINDD research team had been considering and the video has since been changed to reflect this difference.

<u>In-MINDD Profiler Service user Suggestions</u>

The following suggestions were made for the In-MINDD profiler.

- Stents be included under the cardiovascular disease section.

(Stents are used as a treatment for heart disease and while indicative of blocked arteries/heart disease stents themselves would not be classified as heart disease.)

- Name sections such as A1, A2, A3 to help situate users.
- Provide feedback (such as a bar or a percentage meter that would provide feedback to the user about how much of the profiler was completed
- Provide a save and return function.
- Provide online tutors or help wizards
- Positive response to information icons explaining each section.

<u>Completing the Profiler</u>

Participants indicated that they would like to complete the profiler at a place most convenient to the participant. Most participants interviewed thought they would be able to fill it out at home without a researcher present.

"I would have thought people would have been more comfortable doing this online at home. They would have to find the time to come here"

"Honestly I wouldn't feel I would need a researcher with me."

Some issues were raised as to why In-MINDD is an online tool and if it could be offered offline. As with the GP interviews questions were asked about how representative a sample of the community this provides.

"Is there any reason why it has to be an online tool?"

"Will you be getting a good cross section of your community?"

Participants expressed great interest in using the In-MINDD program.

"Would love to (use In-MINDD)"

The preceding quotes indicate participants who are comfortable using IT showing a preference for completing the profiler at home. Participants indicated an interest in participation in one to one usability testing of the profiler.

Diet section

Participant's asked if there was a section for supplements such as multi vitamins, B12 or fish oils. Lean red meat being in the same category as sausage or hamburger meat was found to be confusing. In terms of diet participants interviewed seemed very aware of the Mediterranean diet and what this diet prescribes (brown carbs over white carbs, olive oil over butter etc).

LIBRA (Lifestyle for Brain Health Score)

Participants asked about why the colour blue was used instead of green for consistency with the traffic light system. Participants were confused about the weighting of the risk factors that comprise the LIBRA score.

"That diagram, I don't think it's clear, there must be a better way of representing that information. I'm not sure about the green and amber ideas. If I score high and I'm drinking too much id like that to jump out at me."

Participants were not clear about whether the larger section (mood) was more important for the participant to concentrate on or if mood is always proportionally more important than the other risk factors.

Factors to focus on

LIBRA improvement space
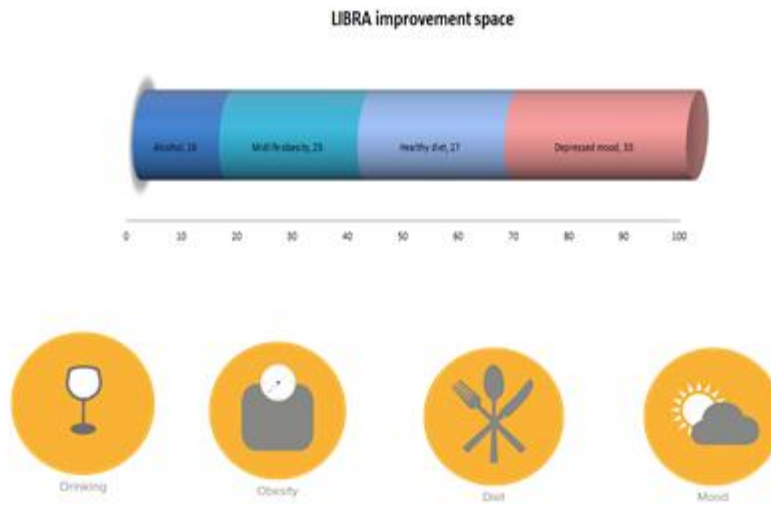
Co-morbidities

This issue has been raised throughout the research. GPs interviewed brought up the issue of co-morbidities. A number of diseases and conditions are frequently seen in the population of people with dementia. These diseases experienced at the same time as dementia but which may or may not be related to that dementia are known as comorbidities. Or presence of conditions such as heart disease and diabetes putting a person at a greater risk of developing dementia.

Social Media Closed Group

There was mixed reactions to social media with some participants using it and some not. The idea of a social media closed group used to discuss In-MINDD issues with other participants was met with mixed reactions. Some participants indicated that a social media closed group would be useful while others were not interested. Some concerns were raised about privacy when using social media. Some indicated they might use some type of forum or group that was not.

Contact from In-MINDD

Participants commented that they would be happy to receive email or text notifications from In-MINDD. Participants suggested that encouragement and monitoring could help to keep the participant using the program month by month.

"I would rather be monitored over the 6 months so I actually see progress or see that I   didn't make any progress and that I got to do better next month. That's just me."

"I think everybody likes to be encouraged. Or likes to see acknowledgment of what they   have done. Or someone to say "you've had a 'poxy' week this week but get back on the   horse next week"."

Health Apps

Participants reported that they did not use specific health-related apps. However a participant with diabetes used an online spread sheet to monitor blood sugar levels. The participant pointed out that the act of monitoring blood sugar helped to keep his blood sugar at the appropriate level.

Implications of co-design

Participants indicated a preference for cognitive activities that involve the aspects of a game such as scrabble or cards. Incorporating gaming elements could help users to engage with goals when using the support environment. It is suggested that the goals offered are written with a positive orientation where possible.

LIBRA Score

- Need to explain the LIBRA score/profiler more clearly to users, e.g. in room for improvement space, there is a need clarify whether it is important or not for users to address one risk factors over another/others.
- The horizontal bar was not found to be straightforward or easy to understand. Perhaps a pie chart or a vertical bar chart/histogram might be more easily understood.

Goals

- Need for clarification around the weighting of goals. If goals are equally important this needs to be made clearer to the user.
- Suggested to incorporate gaming elements.

Frequently Asked Questions section:

A number of issues raised by participants were selected as questions to be addressed in the FAQs page. Other questions that might be considered for inclusion in the FAQ section are as follows:

Q. Is dementia becoming more common?

Q. If I am managing my blood pressure with medication is that the same as managing it through lifestyle changes (with regard to future dementia risk)?

Q. Are some of the risk factors for dementia also risk factors for other diseases or disorders (such as cardiovascular disease, diabetes, stroke, cancer etc.).

Embedding In-MINDD system in everyday practice

- Participants would like to be able complete the profiler at home with supports in place if needed such as:
- Having an email or phone number for assistance with the profiler would be helpful.
- Researchers present or able to provide remote assistance to users updating the profiler.
- Profiler to be completed at a place that is most convenient to the participant

Supports

Participants would like the following supports:

- Monthly updates emails, texts, or questionnaires.
- Messages of encouragement.
- Monitoring (weekly or monthly) over a six-month the period in order to track progression.
- Participants suggested that the GP could send monthly emails to participants however this was found to be unlikely following on from meetings the research team have had with GPs in the past.