MasterMind

Deliverable D3.7

Guidelines on procuring and implementing cCBT solutions

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D3.7 Guidelines on procuring and implementing cCBT solutions

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Guidelines to foster the adoption and implementation of CCBT services

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EXECUTIVE SUMMARY

The procurement process of software and hardware to be used in computer based cognitive therapy (cCBT) is complex.

Careful consideration to how cCBT should be used and by whom, is essential.

The MasterMind project have illustrated the diversity of this process between the different sites. Scotland licences a well-established cCBT program, the Netherlands also uses well established programs. Most sites have developed their own programs that are culturally adapted to their sites.

The four Spanish sites (Catalonia, Aragon, Basque and Galicia) have had a very interesting approach to obtaining the cCBT solution. They have analysed cost benefit and have decided on adapting existing contents to develop a common cCBT solution that is used in their different platforms.

Italy have obtained the cCBT solution from European Alliance Against Depression (EAAD) and slightly modified the solution to the Italian platform.

Open tenure have only been used for part of the solutions because most of the cCBT solutions have either been developed as a part of the implementation process. Scotland and the Netherlands already had solutions that fulfilled conditions of one supplier.

For future cCBT developments it may be worthwhile to consider if the interesting Spanish and Italian experiences could be used to create a business model that combine the ideas from EAAD and Spain. This could be done by developing culturally neutral modules with essential part of different therapies that could be purchased by different countries and used in platforms that add cultural elements to a treatment programme.

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1 Introduction

1.1 Purpose of this document

D3.7 focuses on implementation from a procurement perspective – the process of acquiring (buying) the cCBT. The document also focuses on considerations and guidelines that precede procurement.

ccVC is not a part of this document, and is only mentioned as part of blended care.

Most of the partners that use cCBT in MasterMind have had to procure the necessary tools for it. They have a wide spectrum of valuable experiences that may be of use for other parties that want to procure the tools necessary for cCBT.

Several healthcare professionals in the focus groups, and representatives of the organisations in the semi-structured interviews, indicated that the availability of cCBT solutions on the market currently is vast. It was discussed that due to the availability and lack of quality standards, it is difficult for healthcare professionals and service providing organisations to evaluate quality and added-value of the available solutions (see D5.5, D6.5 and D7.6 for more information).

This report contains the cumulative experiences from the sites in acquiring and procuring the required cCBT solutions to provide telehealth psychotherapy.

1.2 Structure of this document

We start with a short introduction to the field (chapter2) followed by a short presentation of the partners focused on implementation from a procurement perspective (chapter3).

Then we present a summary of major considerations that have to be made ahead of procurement. Subsequently, each of the partners describe their key findings and recommendations. Finally we include an appendix that may serve as a check list ahead of procurement.

1.3 Glossary

ASLTO3	Azienda Sanitaria Locale TO3, Italy
BDI	Beck Depression Inventory
BSA	Badalona Serveis Assistencials, Spain
cCBT	Computerised Cognitive Behavioural Therapy
ccVC	Collaborative care facilitated by Video Conferencing
EAAD	European Alliance Against Depression
EPR	Electronic patient record
GGZinGeest	Stichting GGZ InGeest, Netherlands
ICT	Information and Communication Technology
IT	Information Technology

METU	Middle East Technical University, Turkey
MMind	MasterMind
NHS24	NHS 24, Scotland
NST (NSE)	Universitetssykehuset Nord-Norge HF, Norway (from 01.01.2016 Norwegian Centre for E-health Research (NSE)
Osakidetza	Servicio Vasco de Salud Osakidetza, Spain
PC	Personal computer
PHB	Powys Teaching Local Health Board, Wales
PPI	Public Private Innovation Project
ROM	Routine Outcome Monitoring
RSD	Region Syddanmark, Denmark
SALUD	Servicio Aragones de la Salud, Spain
SCHOEN	Schoen Klinik Bad Arolsen Gmbh & CO. KG, Germany
SERGAS	Conselleria de Sanidade de Galicia, Spain
TUT	Tallinna Tehnikaulikool, Estonia
ULSS9	Azienda Unita Locale Socio Sanitaria N 9 Di Treviso, Italy

2 Background

For many years, cCBT has been studied in research projects in many European countries. We have a considerable knowledge on the effects of cCBT in small projects with selected groups of patients.

There are still many unanswered questions in our understanding of how cCBT works. In spite of concerns about the clinical effects of cCBT, the effects of this tool seem to be on par with medications for mild to moderate depression in specialist care. Contradictory information exists on the effect of cCBT in primary care.

Only the UK, and to some extent Australia, Sweden and Netherlands, have used cCBT systematically on a large scale in the normal healthcare system. In MasterMind, we have implemented cCBT as a tool in the healthcare service on a wide and sustainable scale.

3 Partner description

Below we present a short description of how cCBT has been developed, procured, and deployed by the different partners. This also contains a short description of the partner and how cCBT is used. (For more details on partners, see D 3.1 final scientific protocol.)

Table 1: Partner description with focus on procurement

Organisation	cCBT solution and procurement process
First wavers	
Region Syddanmark	A software implementation was developed as a Public Private Innovation. The program was paid for by innovation funds from the state, and is free for the region until mid-2018. Patients self-recruit to a mail supported cCBT service.
NHS 24 Scotland	Scotland already had cCBT in two of the 14 Health Boards. They have extended the service to four additional Boards. A private company provided the technical solution funded by NHS. Licence costs were based on population. Phase one was procurement of licences, and engagement of territorial boards in integration in stepped care service. Second phase was setting up service infrastructure, clinical governance, managerial structures, staff recruitment, referral routes, and finally marketing of the service.
Stichting GGZ InGeest (GGZinGeest) Netherlands	The majority of the mental healthcare organisations that participated in MasterMind were recruited via the network of the cCBT platform provider of eHealth, Minddistrict. (The rest of the participating organisations use other initiatives). Most of these organisations already offered blended cCBT developed by Minddistrict. Mental health organisations have a contract (for 1-3 years) with the provider of the platform. Minddistrict is one of the largest of about a dozen providers in the Netherlands. Procurement of eHealth solutions is an investment of the mental health organisations themselves, though sometimes the start-up has been funded by state and insurance companies. cCBT is part of regular mental healthcare. Patients are referred to specialist healthcare by GPs. Treatment is reimbursed by insurance companies.
Schön Klinik Bad Arolsen Gmbh (Schoen) Germany	Schön Klinik is a large insurance-based hospital group. Annually, 88.000 patients are treated in 16 clinics. GPs or specialist refers patients to the clinic. Three different services are offered: GetOn (cCBT online training), Depression Online (ccVC), and Relapse Prevention (ccVC). Legal requirements vary between German states. Procurement was from developers, and paid for by reimbursement from insurance companies and a fixed pay per patient. MasterMind pays the major part of deployment costs. The insurance companies are responsible for marketing.

Organisation	cCBT solution and procurement process
Universitetssykehuset Nord-Norge HF (NST) Norway (Norwegian Centre for E-health Research)	After an open tender round with two bidders, a private company developed a platform for MasterMind; MoodGYM was the cCBT program used. Patients could self-recruit, be treated by GPs, with GPs and psychologists, or referred to specialist healthcare where cCBT or ccVC could be used. Patients paid a fee, and the state paid for part of the treatment. A very thorough risk analysis (ROS analysis) was performed. This ROS analysis will be used when the findings from the MasterMind project will be used in larger areas and in the somatic healthcare service.
Second wavers	
Powys Teaching Local Health Board Wales	Wales provided a service that resembles the Scottish service.
Servicio Aragones De La Salud Spain	All the Spanish sites jointly adapted existing therapeutic contents to a new cCBT programme. The sites developed a common cCBT programme to suit their administrative and cultural needs. The programme "Supera tu depresión" (Overcoming your depression) was developed as a joint venture between the University of Santiago de Compostela and the other regions. The cCBT solution is used as a support for many health personnel who prescribe the programme to patients. The programme was integrated in the local EPR platforms of each partner. In Aragón, a private company cooperated with the Public Health Service (SALUD); the company is responsible for maintenance of many of the other IT systems in SALUD.
Servicio Vasco de Salud Osakidetza (Osakidetza) Spain	The Basque Public Health Service (Osakidetza) has collaborated with the other sites in Spain. They also used "Supera tu depresión". A private company (Tekniker) designed the platform, and is responsible for maintenance and technical support. In the future, this application may be integrated in the Personal Health Folder.
Badalona Serveis Assistencials SA (BSA) Spain	As in the other Spanish sites, BSA (Badalona, Catalonia) used" Supera tu depression". BSA had previous experience in cCBT through a public-private collaboration project (Caring.me), and other minor private providers integrated the application in the EPR system within the MasterMind project. The cCBT will be integrated in the EPR system after the cost benefit analysis.
Conselleria de Sanidade de Galicia (SERGAS) Spain	SERGAS also used the programme "Supera tu depresión" jointly developed by the Spanish sites of MasterMind and the University of Santiago de Compostela. The programme was introduced in the electronic medical record of the public system. The platform was the telemonitoring section of the common EPR of SERGAS (Galician Health Service). The programme is prescribed and used by doctors in SERGAS, and works as an interactive part of the EPR.

Organisation	cCBT solution and procurement process
Azienda Unita Locale Socio Sanitaria N 9 Di Treviso ULSS9 Italy and Azienda Sanitaria Locale TO3 (ASLTO3) Italy	The two Italian pilot sites are ULSS9 and ASLTO3, they are both consortium partners in MasterMind. ULSS9 was the clinical site in Veneto, and Arsènal their technical partner. ASLTO3 was the clinical site in Piedmont, and CSI technical partner. ULSS9 and ASLT03 decided to use iFightDepression from the international non-profit organisation European Alliance Against Depression (EAAD) both as software supplier and platform support. The procurement process and related activities with EAAD were regulated by CSI for both clinical sites. The cCBT tool is used in routine care and by patients to monitor their mood and follow their daily activity. When appropriate ccVC is also used.
Middle East Technical University (METU) Turkey	The cCBT solution was developed locally, but modules are from other sites. The target patient group is students of METU referred from the university counselling service (AYNA). The platform was OpenCourseWare.
Tallinna Tehnikaulikool (TUT) Estonia	Estonia has developed and is now using an app with a platform from a private company, and integrating the iFightDepression programme. The programme is used by self-referred patients and as a follow up on recommendation by therapists. The app allows for a chat and mail function with therapist. Patients pay to download the app.

4 Considerations ahead of procurement

4.1 The MAST framework

In the MAST[1] protocol, the authors have identified important preceding considerations to be considered before implementing a telemedicine application. The MAST protocol highlights the following important considerations ahead of procurement:

- Purpose of the telemedicine application.
- Relevant alternatives.
- International, national, regional or local level of assessment.
- Maturity of the application.
- Functions.

With the guidance of the MAST protocol, D3.7 more specifically addresses procurement procedures that are relevant to the implementation of cCBT programmes.

4.2 Scientific documentation

4.2.1 cCBT

4.2.1.1 Therapeutic principles

CBT is a well-established therapy for depression. The effect varies from study to study. Although the effect on depression is less than for anxiety, many studies conclude that the effect on mild to moderate depression is on a par with medication. There is still discussion on whether the effect in primary healthcare is better than treatment as usual.

The literature on the effect of cCBT is extensive; many studies conclude that the effect is no different from traditional CBT. However, it is difficult to conclude on what elements that works, and why.

It is proven that self-help therapies (e.g. bibliographic) have inferior outcomes in certain patient populations compared to therapies with the involvement of therapists, mainly due to patient attrition. The frequently used argument for self-help therapies is that their use requires no support from therapists that are often in scarce supply. Self-help has also been suggested to be used for cost-efficiency reasons.

4.2.1.2 Number of sessions

Studies have shown that there may be an optimal number of treatments for maximal effect. The exact number is not clear, but some studies suggest that more than eight sessions may not increase the effect.

[1] Kidholm, Kristian, et al. A model for assessment of telemedicine applications: mast. International journal of technology assessment in health care, 2012, 28.01: 44-51.

4.2.1.3 Mode of delivery (technologies)

cCBT can be delivered as a computer program or via the internet. There is a multitude of programs available. Few of the programs have had a thorough scientific evaluation in large scale RCTs due to the heterogeneity of depression, and the difficulties in getting large enough samples of patients. In Estonia, a mobile app was developed as part of MasterMind; its strength is its flexibility and availability.

In MasterMind, a wide range of programs were used. Some of the programs were scientifically evaluated, but most were not. All were CBT-based and built on existing elements of cCBT known for their effects.

In general, three types of delivery modality are distinguished: unguided (i.e. complete self-help), guided (either technical, or in the form of asynchronous coach or therapist guidance), and blended (i.e. a combination of guided and face-to-face sessions).

Patient contact can be face to face (i.e. blended), via video (i.e. videoconferencing facilitated), or by chat or mail (i.e. asynchronous). In these therapies, the effect of patient alliance has been studied without any firm conclusion as to which type of patient contact is superior.

4.2.2 Technological platform

As always in the new IT developments, the technology that delivers cCBT is very difficult to evaluate scientifically before it is outdated. As a consequence, the scientifically evaluated programs already seem outdated, although the therapeutic validity of CBT is not in question.

Recommendation:

Strong scientific documentation exists that CBT is effective in treatment of depression. The effect of cCBT is also demonstrated, although the effect is less solid. We still need knowledge on which elements of the programs work and for whom. Nevertheless, as the principles of CBT have proven efficient in treatment of depression, cCBT programs must be based on CBT.

The way that cCBT is presented to patients must be developed in the hope that treatment adherence and dropout rates can be diminished, perhaps by a more personalised flexible and motivational mode of delivery. In addition, the use of new technologies promise efficiency gains, but also gains in accessibility of mental healthcare and reaching people that traditional services are unable to treat.

4.3 Use of cCBT in MasterMind

4.3.1 cCBT use in MasterMind[2]

A condition for being part of the MasterMind project was that partners should use the cCBT solution to treat depression. However, how the partners should use the cCBT solution was not specified so as to give room for site-specific needs and constraints. As a result, the partners applied different delivery models and specific module content depending on the

[2] For detailed information on an overview of the modality and healthcare setting see MasterMind reports D5.5, D6.5 and D7.6.

target population, ambition, and place in the healthcare system. Solutions ranged from unguided to blended care; most made use of guided care with minimal therapist support. The position in the healthcare context varied from a stepped-care approach in primary care to specialist care in mental hospitals, to a combination of primary and secondary care.

4.3.2 Pure self help

Pure self-help, where patients use the programs without any contact with health personnel, has a low response rate, but the program could potentially reach the whole population. Therefore, even if the response rate is low, the number of people reached may be high. There are considerable design challenges in order to motivate persons to use the programs. Australia has had programs for the general population for many years. Beyondblue is an extensive internet site that provides information and support to Australians independent of location and age. The MindSpot Clinic is a free on line service for Australian adults who are have difficulties with anxiety, stress, depression and low mood.

4.3.3 Blended care

The term blended care covers both parallel blended care, where CBT face to face treatment is integrated with cCBT into one treatment (i.e. face-to-face alternating with online sessions), and sequential blended care, where face-to-face treatment is carried out before or after the cCBT.

4.3.4 Assisted self-help (minimal guidance)

In assisted self-help, health personnel recommend the program, and the patients then work on the program on their own. There is a varying degree of assistance, from demonstrating the program, to following up progress and motivating patients to persist.

Different health personnel can assist. As the patients, to a large degree, have to work alone, the programs must be user friendly, easy to understand, and motivate progress.

4.3.5 Guided self-help

In guided self-help, the patient is guided through the program by a healthcare worker. The contact can be face-to-face, by video, e-mail, or chat. This is more labour intensive, but more patients complete the therapy. Patients are motivated by the interaction with therapists, and therefore the cCBT programs need not have as much motivational drive as pure self-help programs.

4.3.6 cCBT as part of a wider variety of therapies

cCBT may be part of different therapies such as group therapies, different types of art therapy, motivational activity therapy, etc. These therapies can be both blended and sequential.

Recommendation:

Before deciding on a program, a clear plan for how and who will use the program must be determined, because this will reflect on the design and content of the program.

With therapist involvement, the better the outcome, but this also seems to increase the cost. The optimal balance between modality, cost, and effect needs to be determined based on the level of session and patient profile.

Homework is a central part of CBT, therefore this must be a part of cCBT. However, the intensity of therapist involvement can vary.

4.4 Supply and development of technical infrastructure

If cCBT is to be used as a sustainable and integrated part of the healthcare system, it is important that the supplier has the personnel and economic resources to carry through the very complex integration process. If the application is separate and not integrated, this aspect is less important, but the cCBT may be less sustainable over time, as it may rely on separate funding. The vulnerability to funding may be outweighed by more flexibility and ability to integrate new technologies faster. However, the effect of the integration and supplier sustainability needs further studies.

4.4.1 Licensing

Licensing programs directly from suppliers that already have a scientifically tested program seem to be a convenient solution. However, careful consideration to copyright, cultural issues and cost of technological and language modifications must be taken into consideration.

4.4.2 In-house developed program

The advantages of developing one's own programs are that the programs are culturally adapted and updated to the traditions of the site, and the programs can be modified as needed without copyright considerations. Most of the partners have developed the programs in close cooperation between private companies and public institutions.

4.4.2.1 Solitary development

The healthcare organisation can develop the programs alone. The MasterMind first wave partners except Norway have used this traditional approach. In the Netherlands, smaller platforms are developed by universities, but they proved less competitive than the big well established commercial spin-off vendors.

4.4.2.2 Co-development

The four Spanish regions grouped under the “Spanish cluster” made an analysis of the existing solutions available on the market. The majority of these solutions were offered on a licence per user basis. Getting licensed programs saves time, because the cCBT software only needs to be translated, and perhaps applied to the existing platform before use. But licensing may hinder local cultural and technical adaptations. In Spain, they decided that a cheaper, more flexible and better integrated solution was needed. They therefore jointly developed a cCBT program, designed from existing experiences within their regions. They used this jointly developed program in MasterMind. Some of the sites integrated the solution in their EPR. In that way they got a culturally relevant program based on cCBT, but the program per se was not scientifically evaluated.

4.4.2.3 Combine elements

Italy got program elements from a German charity EAAD. An extensive contract specified the conditions. They used the program with minor changes to suit local needs.

Recommendation:

In MasterMind, different strategies were chosen in acquiring the technological platforms for offering the cCBT services. This depended on contextual factors, and it is difficult to recommend any generic strategy.

In Scotland and the Netherlands, mature programs were available through licensing. When good culturally and technically suited programs are available, this seems to be the optimal solution, due to reliability and cost.

When no established platforms are available (e.g. due to linguistic, interoperability, or other locally determined aspects), it is advisable to jointly develop the technical infrastructure with other service providers and share the risks, costs, and knowledge.

If programs are licensed from external sources, very careful considerations should be given to legal and data-protection issues, reliability, service support, and continuous improvement of e.g. the design and security to stay up-to-date with technical advancements in the wider society and target population.

If programs are locally developed, the financial stability and trust-worthiness of the developer must be taken into careful consideration.

A future business concept could possibly be to develop high quality common modules and architecture that can be integrated into local technically and culturally adapted platforms.

4.4.3 Integration and interoperability

In MasterMind, integration and interoperability have been major causes of reduced system usability and delay. The technical challenges in integrating a program into a pre-existing platform or EPR system has caused delays in several sites, and often led to sub-optimal working procedures. The more complex the platform, the more challenging is the integration process. However, sites experienced that the more the program is functionally integrated into the existing technical infrastructure (e.g. EPR), the more likely it is that the program will actually be used by healthcare professionals and others in routine care. Integration not only relates to technical interoperability, but also often concerns legal aspects of data security, data ownership, as well as changing the working procedures, roles and responsibilities of staff involved. This topic has the attention of many service providers, regional and national authorities, and even the European Commission (e.g. eHealth Action plan of DG Connect). This requires a concrete evaluation by every site, but enough time and resources should be allocated to this process. In most of the sites, the programs are dissociated from the electronic patient dossier. Integration is preferable, but from a technical perspective it is still difficult.

4.4.4 Internet literacy and accessibility

The internet literacy of patients and their access to the required ICT varied considerably in the MasterMind regions. The level of internet penetration, reliability, and bandwidth of internet access should be taken into account before and during the procurement process. Where and how should patients work with their cCBT homework? In countries with high accessibility and literacy, patients can work with the programs at home. In other areas, it may be necessary to purchase workstations (either stationary or mobile) for use by patients.

4.5 Resources

For delivering cCBT services in routine care, two types of costs can be distinguished. Depending on the care setting and target population, each must be evaluated ahead of procurement, including:

- Investment and start-up costs.
- Recurring and running costs, direct and indirect.

4.5.1 Investment

Investment costs are related to the cost of getting the service into routine practice, and are often one-off costs. In general, the following cost can be expected:

- Analysis and consultancy of current ICT infrastructure and assessment of needs.
- Development costs for integrating the solution into existing infrastructure.
- Initial training of ICT support and end users (i.e. healthcare staff).
- Production of manuals and guidelines.
- Adjustment of working procedures and routines.
- Production loss due to staff training and incorporating new ways of working.
- Changing existing services and working procedures, and replacing them with new services.
- Recruitment of staff if additional expertise or man-power is needed.

4.5.2 Recurring costs

Recurring costs are related to the cost to maintain the services in routine care. These costs can be directly or indirectly attributable to the service. Direct costs include licences (either per patient or bulk), technical support, continuous training (technical and therapeutic), and peer-group supervision. Indirect costs identified include office rent and supplies, communication subscriptions, management and administrative support, therapist time, etc.

4.5.3 Reimbursement

To cater for the above costs, various strategies for reimbursement should be assessed and taken into account. Modalities for reimbursement depend on the healthcare system and governance, and in general include:

- Reimbursement through public healthcare system (i.e. Ministry of Health).
- Private health insurances.
- Out-off pocket by the patient.
- No reimbursement.

In many countries, as has been indicated in the trial reports (D5.5, D6.5, D7.6), the majority of the MasterMind services were reimbursed by either the public healthcare system or private health insurances, or a combination of these two.

Recommendation:

Various costs have to be taken into account when procuring cCBT services. Costs can be one-off (i.e. investment), or recurring to maintain the services in routine practice. Various mechanisms for reimbursement are possible, and often a combination of modalities are available. Investment costs are often not eligible for reimbursement.

It is advisable to develop a business case based on a realistic estimate of market share and target population, investment, recurring costs, and current and anticipated reimbursement modalities and sources. It is good practice to monitor the business case periodically and define scenarios for informed decision making.

4.6 Staffing (technical, clinical)

This section is only concerned with the decisions that have to be made ahead of implementing cCBT. The size of staffing depends on the local infrastructure and the ambitions of the cCBT system. Will the system be an add-on with specially trained technical staff and therapists, or completely integrated into the normal running of healthcare?

4.6.1 Overall structure

As part of the preparation for deployment of cCBT, it is naturally important to decide on the administrative structure that is needed for procurement, deployment and running of the cCBT. The experiences from the MasterMind suggest that the top administrative staff must be well informed about the application. The process from procurement to the day-to-day running of cCBT can be left to more routine administration. The planning ahead of procurement must be an integral part of the whole process of procurement, implementation and running of the cCBT.

4.6.2 Technical staff

All the partners in MasterMind stress the need for technical staff to be involved in all the major decisions related to procurement. Technical staff must be involved all the way through the planning of procurement process. This will ensure good technical specifications for software and hardware products. In many sites, preparations and procurement is an integrated development process, and not a solution that could be bought or licensed. Only Scotland, the Netherlands and Germany had cCBT products that could be used without major technical challenges.

Video used as part of blended care poses technical challenges in most sites, because the video infrastructures still have limitations and are unevenly developed.

4.6.2.1 Therapist

In MasterMind, psychiatrists, psychologists, GPs, psychiatric nurses, health coaches and auxiliary staff are involved in treatment, either alone, in a collaborative setting, or in a stepped care fashion. As a preparation for procurement, therapist staffing must be defined. Who should provide the therapy: patients themselves, auxiliary staff, GPs, psychologists or psychiatrists? What type of therapy will be given: self-help, assisted, guided? What contact should patients have with the health care system: none, mail, chat, face-to-face (alone or in group therapy)? How many sessions should be planned? Is the cCBT solution flexible enough to fulfil the requirements for stepped and/or collaborative care, and the different skills of therapists? What therapist do we have and what are their skills? All these considerations must be part of a procurement process.

Recommendation:

Expenditure on procurement of cCBT must be based on ambition, infrastructure, program integration, technical maturity, staffing and running costs.

Ahead of procurement, leadership, and considerations on the qualifications and availability of technical and therapeutic staffing are paramount.

Involvement and support from the organisational leadership is of the outmost importance.

Implementing cCBT at scale is extremely complex, both from an organisational and technical point of view; therefore enough time must be allocated to this process.

5 Evaluation

Continuous evaluation and monitoring is an integral part of all changes in the management and technical solutions used in healthcare. The evaluation of cCBT should include the following elements

- Clinical effectiveness.
- Patient needs and satisfaction.
- Usability and user-friendliness for both patients and professionals.
- Professionals' satisfaction.
- Flexibility, adaptability, and interoperability of the solution.
- Need for technological and administrative support.
- Safety and security.
- Use of standards and clinical guidelines.
- Availability of training materials, manuals, and information.

In MasterMind, there has been an extensive scientific evaluation reported in deliverables D3.5, D5.5, D6.5, and D7.6. Various instruments are available to produce (e)health technology assessments and business cases. In MasterMind, the MAST methodology[3] was applied. Please refer to the study protocol and subsequent deliverables for more information on the evaluation.

5.1 Quality

A cost-benefit analysis is difficult when cCBT is to become part of the normal running of a healthcare system.

The evaluation of a scientific well-controlled experiment is different from assessing the often complex and iterative nature of implementation processes. There is a risk that gathering information to get answers on the quality of the therapy and implementation process will hamper clinicians' and patients' day-to-day clinical work. Careful consideration should be given to how to secure good quality data with the minimum effort for patients and therapists. There is no single solution to this, but Routine Outcome Monitoring (ROM) systems have proven beneficial in those organisations in which ROM is already routine practice.

Recommendation:

Careful consideration should be given to the cost-benefit of evaluating cCBT.

There is a risk that data collection procedures for informed decision making will interfere with daily operations, and negatively affect clinicians' and patients' day to day clinical work.

Careful consideration should be given to how to secure good quality data with minimum effort for patients and therapist.

[3] Kidholm, Kristian, et al. A model for assessment of telemedicine applications: mast. International journal of technology assessment in health care, 2012, 28.01: 44-51.

If material needed for cost benefit analysis can be integrated as part of patients' homework and normal clinical registrations, the chances of good quality outcome data on an implementation process is increased. As such, Routine Outcome Monitoring systems prove to be of value, and can be exploited to facilitate informed decision making and implementation process.

6 Legal considerations

Legal considerations are essential both in relation to contracts for procurement and operation of the applications, and the storage and management of personal sensitive information. In the new and complex field of ICT in mental health, there are many technical challenges that need good contracts to prevent major disagreements and to safeguard that all partners receive safe and high quality treatment. The pitfalls are many: copyright, licence, invitation to tender, delays, dysfunctions. For an in depth description on the legal framework on eHealth, see e.g. The EU legal framework on eHealth[4].

The eCommerce Directive[5] provides a legal framework to ensure the free movement of so-called 'information society services'. It sets information requirements for information society service providers, rules on commercial communications, on contracts concluded by electronic means, and on the liability of intermediary service providers.

In order for a telehealth service to qualify as an information society service, it needs to be a "service normally provided for remuneration, at a distance, by electronic means, at the individual request of a recipient of the service"[6].

According to this framework, when providing cross-border telehealth within the EU, healthcare professionals should take into account the following aspects:

- Licensing: Does the telehealth provider also need to be licensed/registered in the Member State of the patient?
- Data Protection: What are the conditions for the legitimate processing of personal data related to health?
- Reimbursement: Will the cross-border telehealth service be reimbursed?
- Liability: What is the liability regime applicable in case damage arises?
- Relevant jurisdiction and applicable law in case of damage: What are the relevant jurisdiction and the law applicable in case damage arises?

More information can be found in the Commission staff working document[7] on the applicability of the existing EU legal framework to telehealth services and the eHealth action plan 2012-2020[8].

6.1 Procurement

Procurement is supposed to be on a tender. However, there are few sites that have a normal procurement / tender process, because the technology is specialised, with often only one solution that meets the criteria. Most of the applications have been co-developed with an academic institution or with other specialised bodies directly linked to MasterMind. In Scotland, there is only one application approved by the NHS. In the Netherlands, there are more competing applications, and mental healthcare organisations are free to choose

4 http://www.euro.who.int/__data/assets/pdf_file/0008/138185/E94886_ch13.pdf?ua=1

5 Directive 200/31/EC of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market - OJ L 178, 17. 7. 2000, p. 1.

6 Article 2(a) of the e-Commerce Directive and Article 1(2) of the "Regulatory Transparency Directive"

7 http://ec.europa.eu/information_society/newsroom/cf/dae/document.cfm?doc_id=1251

8 http://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52004DC0356&from=EN

from more than a dozen providers. Many of the providers have chosen the Minddistrict platform because of the many modules for different mental health problems, and the integration of VC. In all the other countries, the applications were developed jointly with an academic institution or a private partner that have been part the process during development, and either a public or private healthcare provider.

6.1.1 EU legislation

Research and innovation, including eco-innovation and social innovation, are among the main drivers of future growth, and have been put at the centre of the Europe 2020 strategy for smart, sustainable and inclusive growth. Public authorities should make the best strategic use of public procurement to spur innovation. Buying innovative products, works and services plays a key role in improving the efficiency and quality of public services while addressing major societal challenges.[9]

The basis for procurement within the EU is described in factsheet from the Commission on Public Procurement [10] and the Directive 2014/24/EU, Article 18 and 58[11].

The thresholds applied to tenders whose monetary value exceeds a certain amount can be found in the following documents: EU Public contracts, Rules & procedures [12]; the EU Commission's factsheet on procurement[13] describes how the limits for open tender depend on the type of application.

6.1.2 National legislation

The legislation on tenders is not only at EU level, there are also varying national rules. (See section 7).

6.1.3 Licence conditions

The licensing conditions were only applicable to Scotland, and to some extent Italy. In section 7, the Italian partners have given a thorough description of their contract with EAAD.

The Spanish cluster has developed a sharing agreement. This agreement regulates the use of the contents from MasterMind in routine practice at their sites; it also gives a framework for the management of IPRs in case third parties are interested in using these materials.

6.1.4 Breach of contract

Naturally, there should be clauses for breach of contract, but this is a difficult task, as for the most part the cCBT solutions are products that are being developed as a part of the implementation process.

[9] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014L0024

[10] https://ec.europa.eu/growth/single-market/public-procurement_en

[11] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2014.094.01.0065.01.ENG

[12] http://europa.eu/youreurope/business/public-tenders/rules-procedures/index_en.htm

[13] https://ec.europa.eu/growth/single-market/public-procurement_en

6.1.5 "In house"

As mentioned, most of the technologies in MasterMind were a mixture between academic developers and private companies already involved in the use of other applications within the healthcare system.

6.1.5.1 Tender or not (limits)

Most of the applications were small tenders within some organisational cooperation. The software technologies are still being developed within a complicated network of prior cooperation, cultural specificities, and knowledge of healthcare solutions within the countries. The only exceptions are Scotland and the Netherlands, and to some extent Italy and Estonia. In Scotland, there is a de facto monopoly, because only one party has been judged to have enough scientific proof of therapeutic quality. In the Netherlands, more suppliers offer competing cCBT solutions. The choice of supplier is influenced by content and price.

It is not surprising that in most countries except for the Netherlands, cCBT solutions are not competing for tender in an open marked. cCBT technology is still in its early stages. Neither the technology nor the quality of the clinical outcome seem to help potential acquirers decide that one supplier is better than another. The consequence is that in most sites, factors other than quality and price decide which supplier gets the job.

6.2 Privacy and Data protection

6.2.1 EU regulations

In general, personal data can only be gathered under strict conditions, and only for legitimate purposes. Persons and organisations collecting and managing privacy sensitive data are obliged under EU law to protect the data from misuse, and must respect the rights of the data owners.

Health data is highly privacy sensitive. Therefore, eHealth interventions and applications must be designed in such a way that the users' privacy is safeguarded. By means of the Data Protection Directive[14], common rules have been established to ensure high standards of data protection in the EU. In an attempt to make this legislation accessible, a Code of conduct[15] has been developed to facilitate awareness and compliance at EU level for stakeholders in eHealth (app) development.

An eHealth network has been established to enhance interoperability between various forms of eHealth (e.g. EPD and continuity of care) and to facilitate access to healthcare.

6.2.2 National regulations

Most countries have specific legal requirements that specify data storage requirements.

For example, all mental health organisation in the Netherlands have legal experts who work out a data processing agreement with the eHealth provider to assure privacy and safety

[14] The 'Data Protection' Directive, Council Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ 1995 No. L281/31. http://ec.europa.eu/justice/policies/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf

[15] https://ec.europa.eu/digital-single-market/en/privacy-code-conduct-mobile-health-apps

rules are followed. The software should be CE marked, and the data should be safe according to European legislation.

In Norway, as a part of the preparation for cCBT, a detailed risk analysis (ROS analysis) must be conducted and documented.

Recommendation:

From the MasterMind project, it is difficult to draw any clear recommendation on the legal aspects of procurement, because most sites developed their application as an extension of former collaboration with other projects or, as in Denmark or Scotland, had particular reasons why tenders were not a possibility.The Netherlands was the only site where cCBT companies competed in a market.

Naturally tenders and data protection should comply with national and EU regulations if or when major cCBT public procurement would be undertaken.

In addition, and towards future technology procurements, it is strongly advisable to take into account the Code of Conduct for app developers, and the (forthcoming) recommendations on interoperability and guidelines in the area of eHealth by the eHealth Network.

7 Description of legal consideration by partner

7.1 Region Syddanmark

One of the major benefits of the selected model (PPI) is that the joint knowledge of our organisation and of the software vendor can form a synergy pushing the technology forwards. Additionally, knowledge developed and used by the public healthcare sector is transferred to industry. However, there are legal pitfalls, which must be addressed with severe stringency. Most prominent is the issue regarding security of sensitive data. For this reason, a clear data-handling agreement was established, binding the software developer to adhere to Danish and European laws on handling of sensitive data. Another issue was state aid: a detailed agreement was established between the partners, regarding contributions of intellectual properties and economic flow. Finally, a contract between the partners tailored to the PPI framework was signed.

7.2 NHS 24 (Scotland)

The primary legal consideration was around obtaining the software licence for the cCBT solution and ensuring that the purchasing process complied with the legal requirements around procurement within a public sector organisation. NHS in Scotland is required to comply with legislation which includes EU Directives on public procurement and the Procurement Reform (Scotland) Act 2014. In addition to this, there are also various policies and procedures and internal governance structures for the procurement process within each of the NHS Health Boards.

To speed the procurement process, and as the selected cCBT solution was already being used within two of the 14 Health Boards, it was decided to waive the public procurement process and secure the licence through a sole source procurement. This required the development of a Sole Source Justification or a waiver to the public procurement process. The waiver was justified through the available evidence of the selected product, and the need for continuous service within the two Health Boards offering the cCBT service prior to MasterMind.

In addition to the legal requirements around procurement, consideration was given to data protection and the information stored within the cCBT solution. The protection of patient information is governed by the Data Protection Act 1998, the Human Rights Act 1998, the Infectious Disease (Notification) Act 1889, and Adults with Incapacity (Scotland) Act 2000 to name just a few. It was important that any cCBT solution acquired would meet the policies, legislation and organisational standards identified in these documents, as well as the internal information governance policies within each of the participating Boards.

7.3 Stichting GGZ InGeest

All the participating mental healthcare organisations were already using cCBT solutions before the start of the MasterMind project. In the procurement process, the focus was mainly on the content of the solutions. Legal considerations that were taken into account are based on the fact that everything that is applicable for ‘offline’ care is also applicable for online care. Specific eHealth standards are still scarce. According to the standards, eHealth is only allowed within the framework of an existing treatment alliance. When using electronic devices in the treatment setting, there are more parties involved than the

therapist and the patient; this makes the question of liability when something goes wrong more complex than with conventional methods. Privacy protection rules for patients (WBP and WGBO) apply for regular mental healthcare and eHealth as well.

The provider of the platform implemented ISO 27000 and NEN 7510 security guidelines. They use different methods for security, such as encryption, separate production and development environments, authorisation, user name and password, different databases for clients, firewalls and electronic logbooks[16].

7.4 Schoen Klinik Bad Arolsen Gmbh

The legal framework for the conduct of online therapy and training is non-transparent in Germany. Varying legal frameworks are in place for the different states. The Hessian rules of professional conduct dictate that a treatment cannot be performed from a distance alone. Therefore, we implemented on-site intake and diagnostic interviews for the "Depression Online" programme. This was not necessary for the other two services. There is no legal groundwork for reimbursement of the services by health insurance companies; therefore selective contracts had to be concluded with the participating health insurance companies.

7.5 Universitetssykehuset Nord-Norge HF

The legal undertakings were much more time consuming that anticipated. A tender was undertaken, which followed local regulations on public acquisitions. The tender contained clauses on delays and quality standards. However, as the project developed, there were many delays where the clauses could not be applied because it was not clear who was the responsible party in the intricate integration process between the public system and the private company. The second large legal undertaking was to secure data and produce a ROC analyses and get that approved by the healthcare provider. However, now that we have worked through the legal procedures, MasterMind has helped to pave the way for future healthcare ICT applications.

7.6 Powys Teaching Local Health Board

Any public procurement in the UK is subject to conformance with the national procurement policies and regulations, and must be based on "value for money", defined as "the best mix of quality and effectiveness for the least outlay over the period of use of the goods or services bought". There is a legal framework which encourages free and open competition and value for money, in line with internationally and nationally agreed obligations and regulations. In line with these procurement policies and legal frameworks, Powys Teaching Health Board conducted a single tender process, as from the outset of the pilot there was only one solution that met the specified criteria; this, along with the monetary threshold, justified the single tender process.

[16] https://www.raadrvs.nl/uploads/docs/Achtergrondstudie_Juridische_drempels_voor_toepassing.pdf

7.7 Servicio Aragones de la Salud

Procurement

The Spanish Cluster entities had to comply with the Law of the Public Sector Procurement (Ley de Contratos del Sector Público,) Royal decree 3/2011, 14th November 2011.

The adaptation of the contents was made by professionals from the four regions under the "Spanish Cluster" teamwork. Once these contents were finished, the Spanish cluster looked for a company to develop the audio-visual materials. The whole budget for this service did not exceed 18,000 €, so a minor contract was suitable.

Personal data

The Spanish Constitution (1978) includes an article (18.4) which claims that the law shall restrict the use of informatics in order to protect the honour and the personal and family privacy of Spanish citizens, as well as the full exercise of their rights. It also includes an article (43) related to the right to protection of health.

Other laws and directives expand these fundamental rights, the most important are the Personal Data Protection laws:

- General Law 14/1986, 25th April, about healthcare. It includes the right of patients to be informed, and the confidentiality of health-related information.
- Organic Law 15/1999, 13th December on the Protection of Personal Data; Article 7 deals with data related to sensitive information. In the Royal Decree 1720/2007, the Rule Development of Personal Data Protection Law was approved. This Decree aims at regulating possible risks to personal data treatment. It implements European Directive 95/46/CE related to the protection of personal data management.
- Law 41/2002, 14th November. Basic regulatory law about patient autonomy and the rights and duties in terms of clinical information and documentation.
- Royal Decree 1720/2007, 21st December. Approval of the regulations for the development of OL 15/1999. This Decree updated the legal framework for personal data management, treated by both automatic and non-automatic procedures.
- Royal Decree 3/2010, 8th January. Regulation for the National Scheme of Security in the framework of Electronic Administration. The main goal of this scheme is to define the general conditions to achieve confidence in the use of electronic services by the public administration.

7.8 Servicio Vasco de Salud Osakidetza

The legal aspects were mainly considered during FI STAR project. The application developed by Tekniker fulfilled the privacy and confidentiality requirements specified by Osakidetza, ensuring that patient-related health data remains within its own information system. Although the application has been developed by an external provider, patients' information is securely stored within health provider's boundaries, so no patient data is externalised.

In addition, the online application development was guided by Osakidetza, ensuring that the final solution was compatible in terms of interoperability.

7.9 Badalona Serveis Assistencials

BSA is a public organisation whose sole shareholder is the City Council of Badalona. BSA must follow the rules applying to the Catalonian public sector; these are quite restrictive compared to the private sector.

The applicable law is the Public Sector Procurement Law from 2007 that aims to ensure that the money spent by the public sector follows a set of principles and is spent in the best way. That law sets the threshold required for public procurement at 50.000€. For amounts lower than that, which is the case here, internal procurement rules ask for three different proposals in order to choose the best option to implement. The selection criteria are according to pricing and suitability.

7.10 Conselleria de Sanidade de Galicia

In our country, under Organic Act 15/1999 of 13th December on the Protection of Personal Data, clinical data are considered data requiring a high level of protection.

The cCBT is a health programme that includes high level data pertaining to the mental health of patients, and therefore requires a system that ensures secure access and rules out free access or any access that does not require identification of those accessing the data.

Doctors access the data using a digital certificate issued by the FMNT (Spanish Mint), a public agency under the Ministry of Finance and Public Administrations which among other things provides certification services. This certificate unequivocally identifies the professional accessing the programme data.

Patients are given a username and a password to enter the patient portal. Every time the patient accesses the platform, as well as the username and the password, a PIN is requested that the patient will receive on their mobile phone (which he is required to provide at the time of prescription). This PIN is different for each login attempt and expires after a few minutes.

The cCBT program is part of the electronic medical record of the Galician Health Service, which ensures full compliance with Organic Act 15/1999 currently in force.

7.11 Azienda Sanitaria Locale TO3 and Azienda Unita Locale Socio Sanitaria N 9 di Treviso

The procurement process related to the cCBT tool “iFightDepression” was managed by the technical partner CSI Piemonte for both the Italian pilot sites, Veneto and Piedmont. So the legal considerations are the same for the two Italian partners, ASL TO3 and ULSS9.

Use of iFightDepression

EAAD granted to the two partners a non-exclusive right to use the provided materials, subject to the following limitations:

- Cooperating partners use the provided materials solely to attain the aims of public utility described in the cooperation agreement. Cooperating partners shall neither act commercially nor in their own pecuniary interest. The purpose of the material is the advancement of public health, education and research, and aims to promote the welfare of people suffering from psychiatric diseases, in particular depression.

- Any other form of use of the provided materials needs to be approved by the EAAD (Board of Directors). In particular, a transfer of the provided materials or a transfer of the granted rights to third parties or a sub-licensing of the provided materials may not be allowed without the prior written approval of the EAADs Board of Directors.
- The provided materials shall not be sold for monetary or any other value, nor be forwarded to others.
- Cooperating partner may adapt the materials provided according to local needs. Such adaptations were made in line with the corporate identity of EAAD and the iFightDepression brand, and were agreed upon with EAAD. The realisation and development of such adaptations shall be part of a separate agreement between the parties.
- All rights that have not been explicitly granted to cooperating partners by the agreement are reserved to EAAD. The cooperating partners agree that EAAD owns the copyright of the iFightDepression tool, the website, and all other iFightDepression material, including IP material.
- EAAD reserves the right to revoke the use of the provided materials, especially if cooperating partners uses the material in breach of the agreement.

The granted potential use of iFightDepression self-management tool and website is limited to access to the tool that has been localised in Italian language by the cooperating partners, via a separate user account installed for separately transferred user data (username, password) and to use the functions of the tool and the iFD-website, with a specific section localised in Italian, that is made available and run in the ICT infrastructure on servers of EAAD.

The copyright and all other rights, in particular intellectual property rights, belong to the EAAD in relation to the iFightDepression tool, website and related materials (including IP), and will not be transferred.

The ifightdepression.com website and the iFightDepression self-management tool are to be provided free of charge for all users; other arrangements require a separate agreement.

Copyright

EAAD maintains and safeguards the copyright inherent to the iFightDepression tool, the website, and all related materials, including IP material.

The cooperating partners on their part are obliged to support EAAD in safeguarding the copyright, and to inform EAAD about any existent or imminent violation of the copyright.

Cooperation partner is allowed to use the provided materials or parts of the provided materials for public relations, when this happens for the purposes described in the preamble.

Liability

As EAAD is a registered non-profit organisation with charitable status, the liability of EAAD, its Board of Directors and employees for damages or loss suffered by final users from the cooperating partners because of the use of the iFD platform in the MasterMind clinical trial, were excluded. This exclusion does not apply to damages or losses attributable to intentional or grossly negligent breach of duty. Liabilities for loss of profits, saved charges, claims by third parties are excluded. In particular, EAAD and its Board of Directors are not

responsible for any single patient using the iFD tool and experiencing any harm / other unpleasant situations occurring during the cCBT care treatment.

7.12 Middle East Technical University

The service is implemented under a government funded state university. Recruited patients are referred through the university counselling service, AYNA. Hence the liability is contingent upon the university offices. A protocol is signed between the managing director of MasterMind at METU (Dr. Gokcay) and AYNA, to direct depression patients toward Top Sende, the cCBT implementation we created. The patients we receive keep their places in the waiting list of AYNA. Due to this, legal aspects imposed as a result of the MasterMind project have been negligible. We used a lot of precautions in filtering the patients referred to us. Perhaps because of this, the patient flow into our system has been much less than anticipated.

7.13 Tallinna Tehnikaulikool

A legal confirmation from the Tallinn Medical Research Ethics Committee was needed to start piloting the project. Also, signed consent from healthcare professionals, patient and head of the GP or psychological centres was required. A programme has to be evidence-based in order to provide it to patients.

8 Key findings and important lessons learnt from each partner

8.1 Region Syddanmark

Including all those responsible for deliverables in the project group from the beginning improved the final product. Also, having the specialist psychologist responsible for the manuscript work together with the designers as the first step in the process focused the project on the users and the therapeutic content. However, it was very difficult to translate the requirements from the user centred and therapeutic design to the developers. There was a lack of common terminology, and to some degree even a lack of respect for each other's work.

A longer and more thorough planning process should have been included before starting development and the other parts of the project.

More time and effort should have been invested in defining expectations given that this was a PPI, and not a traditional supplier relationship.

At least one more iteration should have been added with a pilot real life test, of the program followed by a correctional phase and relaunch.

For this project, leadership backup and implementation strategy has worked well, but due the compressed timeframe of the project, actual organisational implementation was established late. It would have been an advantage to have that well worked through, possibly even before initiating the project.

Given that the patient pathway was organised with self-referral, the communication task was very significant. Sufficient resources were not allocated for this task, which was initially underestimated.

8.2 NHS 24 (Scotland)

During the procurement process, there were delays encountered due to the number of people and organisations involved in the process, as well as a dependence on key individuals with the expertise to provide assistance and guidance as required. These individuals had workloads, of which the procurement of cCBT was only one of many priorities. Procurement of the cCBT took longer than anticipated, mainly due to the lack of a clear understanding of the procurement process within various organisations. A key lesson learnt therefore would be to ensure that the complexity of the process is not underestimated, and an understanding of what is needed is developed before starting. The time it will take to obtain a licence should also not be underestimated, and allowances for this should be built into the implementation schedule to ensure that the potential negative impact is minimised.

8.3 Stichting GGZ InGeest

Some of the key points are:

- Uniform technical standards at a national and European level: The different systems that are used within an organisation are (initially) not connected, and data is not

automatically exchanged between different systems; this leads to fragmentation, inefficiencies, errors, and unnecessary duplication of work. The development of linking software such as 'Koppeltaal' is very important for both the therapist and the patient in the implementation phase, but also for maintenance of eHealth.

- European data protection guidelines: an obligation to perform a risk analysis for the processing of personal data; reporting of data breaches within 72 hours to a supervisory authority; and the right to require that all personal data can be erased on request of the owner (right to erasure).
- Quality marks for platforms and apps to ensure reliability.

8.4 Schoen Klinik Bad Arolsen Gmbh

One of the most important findings was that a blended treatment seems to be the best way of treatment for both patients and therapists. Additionally, therapists have to have an intrinsic motivation to conduct online therapy, and not being forced to do it. The complete implementation into a fixed system is time consuming, but necessary for the maintenance of the treatment. Nonetheless, resources have to be allocated in order to help the first stage of implementation, so that it is not only being regarded as more work for the administrative staff. The implementation is unlikely to succeed without any investment. The whole organisation has to be informed about the expected advantages of the innovation, and must be regularly updated about the current status. The implementing site has to think about incentives for therapists working as online therapists, such as working from home, frequent supervision and team meetings, and flexible working hours. Not only do patients need a fully functioning ICT service that can be contacted in case of technical difficulties, but also the therapists in order to avoid frustration. Patient recruitment seems work best through broad media campaign (see Get.On) or direct personal contact from the health insurance case manager (see "Depression Online"). Collecting data in an independent system is regarded as being helpful within the implementation process, in contrast to trying to collect this directly from the clinic internal patient data system.

8.5 Universitetssykehuset Nord-Norge HF

Norway experienced severe challenges when attempting to integrate MasterMind questionnaires into a translated program.

The process of preparing for integration of cCBT into the healthcare system takes time. It is a very different process than conducting a limited research programme with motivated patients and staff. Planning should take into account both technical, work force, motivational and economic considerations. This process is extremely time consuming, because delays in one part of the preparation process can affect all the other parallel preparatory tasks. Realising this, it is tempting to have a very simple integration process. However, limited integration runs the risk of not being sustainable, because the new therapeutic system it is seen by leaders and health care personnel as "outside" the normal healthcare system. This dilemma is pressing in a short-term project such as MasterMind.

When scientific data collection is a large part of an integration project, the demands increase on healthcare professionals and patients, and the chances for withdrawal from data collection increase. Good data is required, but a thorough consideration should be given to collecting the minimum of data necessary to prove the efficacy of the application. If data can be collected as part of an automated process, thist is preferable.

8.6 Powys Teaching Local Health Board

As with many areas of ICT and technological developments, the marketplace is ever changing; it is now much more competitive, meaning that our procurement approach needed to reflect this, and become open for tender applications against a clear specification while conforming with NHS Wales and national procurement policies, standards and procedures.

8.7 Servicio Aragones de la Salud

The technologies are mature, and there is no technological challenge to implement this kind of service.

The interface must be attractive, but should not be very ground breaking, as it might become out-of-date very quickly.

The tool must be based on standards, and must be compliant with a responsive design.

The design of the service must be piloted, and be adapted to each organisation (allow some degree of parameterisation), and not the other way around. If the solution and the protocol are not flexible and do not allow changes, small problems will become barriers.

8.8 Servicio Vasco de Salud Osakidetza

Two main learning points can be extracted from our experience which might guarantee the sustainability of the cCBT service:

- The clinical content and workflows of the cCBT have been defined by front-line healthcare professionals with remarkable expertise in the field -> clinical appropriateness and validity is assured.
- The functionalities of the cCBT solution have been tested within Osakidetza's information system (real environment) -> the solution meets the particular technical specifications of Osakidetza.

8.9 Badalona Serveis Assistencials

The most important lesson learnt:

- A better and more complete program is achieved by sharing knowledge and experiences.
- Sharing resources means saving costs in development.
- It is cheaper to develop your own programme together , rather than paying licences for other existing programmes.
- Develop a programme tailored to your culture.
- On the economic side, an optimisation of the resources should be realised by reducing the number of doctor visits and hospitalisations, the use of medication, and the degree of absenteeism at work. These reasons are well received by management and decision makers, especially in an economic crisis context.

- A single program for all Spanish regions is more useful than each one having their own, and, of course, working together we get a larger number of patients with different environments to test the program.
- The use of ICT-supported monitoring programs allows managing patients in a more efficient way with positive outcome both for patients and healthcare professionals, and also for health organisations.

8.10 Conselleria de Sanidade de Galicia

The most relevant aspects for a proper implementation of the project are:

- Make a firm commitment on the part of the organisation in order to implement Mastermind.
- The continuity of the team in charge, as well as having well-defined responsibilities throughout the whole study.
- A fluent, fast coordination between collaborators and organisation so as to be able to give an efficient response to the feedback provided by those participating in the project.
- Technological simplicity to facilitate acceptance by professionals and patients.

8.11 Azienda Sanitaria Locale TO3 and Azienda Unita Locale Socio Sanitaria N 9 di Treviso

The findings of the two sites have been joined because their findings to a large extent are common.

The main lessons learned regarding implementation and organisation pertain to a large variety of factors; they are reviewed here briefly, but are not exhaustive.

Regarding the MasterMind services realised with the cCBT tool iFightDepression© licensed by EAAD, and the ccVC tool Easymeeting©, in our experience various factors should be carefully considered:

- Finance: financial support is needed for cCBT implementation. Regarding the economic and financial aspects, in Italy the healthcare services provided by the Local Health Authorities received a partially or total reimbursement from the regional government following the guidelines and rules established by the NHS. Telehealth services do not receive any form of reimbursement, except for several specialist disciplines which do not included psychiatry.
- Ad hoc training sessions and continuous monitoring of the study are key aspects facilitating adherence to the project. To realise this, it is necessary to have economical resources, adequate technical equipment, and permission and support of all stakeholders involved.
- Engaging and educating therapists and other stakeholders, increasing communication, and fitting the cCBT to routine service:
  - The clinical target of these services (patients affected by mild to moderate depression) typically first approach GPs; thus, the first important thing is to foster collaboration with a larger number of GPs and try to motivate them.

  - In addition, it is relevant to involve a wide spectrum of health professionals in our unit: not only psychiatrists, psychologists and GPs, but also psychiatric nurses, professionals and experts in psychiatric rehabilitation, and professional educators.
- The role of the two dedicated figures of the Mastermind team was crucial; health professionals and patients can constantly asked for support from them.
- Engaging healthcare professionals and providers: to engage mental health specialists and GPs, more communication between stakeholders, and sharing international guidelines such as NICE about mental Health.
- Engaging healthcare professionals and providers with user-friendly tools. Major difficulty concerned the involvement of GPs who, especially at the beginning of the project, perceived Mastermind as an added chore rather than a resource and a prevention and education tool which can reduce accesses to the doctors' offices. It was solved by a greater commitment and involvement of mental health specialists, in particular in the enrolment phase, but the number of specialists who participated in the project was limited compared to what was expected.
- Setting up the technical services: it is important to have user-friendly tools, at different level: users, GPs and specialists. Many GPs and specialist who found some user difficulties decided to not use Mastermind services at the beginning of the project.
- Patient recruitment for cCBT, and creating c-CBT accounts: to help GPs to screen for common mental health disorders, it is important to consider having some mental health professionals (psychologists) to help them to do this in their office, as GPs are often short of time.
- Organisational issues: every change in the organisational needs reinforcement and time to be accepted by people working in it; more time and educational activities and reinforcement is very important for the implementation of new services, especially telehealth.
- Collaborative communication between GPs and mental health specialists has been difficult and complicated by the lack of time: it could be interesting to offer more space for learning with both professions, to share and understand their different points of view.

8.12 Middle East Technical University

Although 7% of the patients finished the intervention, and 15% participated in it half-way through, BDI scores dropped, statistically significantly ($p<0.01$), by the order of 7 points. So for some participants, the cCBT intervention has been helpful. However, these statistics are not adequate to launch a country-wide service to all university students. There are two barriers here:

- The technical quality of the service may be turning participants away; we need to evaluate that. The current service is geared as a regular course, but maybe the users expect a more professional service.
- Sharing their personal details over an Internet service has a stigma for participants. It takes several email exchanges to convince them that their privacy will be respected, and the data is anonymised. We need to work on this more, on how to provide a more trustworthy appeal.

8.13 Tallinna Tehnikaulikool

Implementation of cCBT service as a provision of telehealth services shall be proved and supported by the State, including solution of technical, financial and legal aspects.

Also, to be considered, that the number of depressed patients using mCBT was higher than cCBT.

Two log-in systems makes the process of patients recruitment complicated, as many professionals frequently forget passwords.

9 Recommendations for other regions from each partner

9.1 Region Syddanmark

Time

It is of vital importance not to underestimate the complexity of implementing cCBT, particularly if software development is included in the process. This calls for a realistic timeframe for the project. There are many tasks and many stakeholders involved in developing and implementing a new treatment. Preferably, a long term plan should be agreed upon at the beginning. In case this is difficult, check points could be included as an exit strategy, such that it is possible to stop the project at certain time points.

Learn from others

Prominently of course, the MasterMind project includes a treasure trove of knowledge and experiences. Additionally, other projects will deliver valuable information such as the InterPsyk project which describes five cCBT clinics in five different countries in Europe. When finished, the ImpleMentAll project will include specific tools for tailored implementation of cCBT. Finally, there are now clinics in many places in Europe, which are usually very helpful.

Leadership backing

The importance of management backing cannot be underestimated. Discussion of practical implementation and organisational issues, including reimbursement models, should have its own early phase in a cCBT project.

9.2 NHS 24 (Scotland)

It is important to not underestimate the complexity and amount of time the process will take; ensure that extra time for this is built into the implementation plans.

Ensure that those with the right expertise in procurement are involved at an early stage.

Those leading the service implementation or project management need to build up an appropriate understanding before starting the procurement process, with a clear idea of what will be required and how best to proceed within the time restrictions defined within the project.

9.3 Stichting GGZ InGeest

- Big financial investment, the need for more (financial) space to innovate within an organisation, initial costs (equipment, training professionals), project costs (e.g. project leader, integration between application and electronic patient file, training of staff), structural costs (e.g. hardware, licence costs, help desk, management and maintenance, hosting).
- Discussions with health insurance companies for reimbursement and stimulation of eHealth.

- Good collaboration and communication with provider to influence technical and content development.

9.4 Schoen Klinik Bad Arolsen Gmbh

In order to find the fit of the service with the local environment, do not focus too much on complete system integration. A simple system introduced without too much development and programming effort might be used as a test to make sure that the content of the treatment actually fits the patients' and therapists' needs. Put effort into system integration, etc., only if this is the case.

If you can, use mass media or direct personal contact as your way to recruit patients.

Put effort into informing all those involved, even if only marginally, about the advantages of the innovation, the next steps, and the first successes.

9.5 Universitetssykehuset Nord-Norge HF

The complex and sometime messy process of deciding on implementation and procurement of a new part of the healthcare system is very complex.

If the system is to be fully integrated in the healthcare system, the number of variables that can fail and the time requires are daunting. To persuade leaders and staff that a new application of technology is worth using on a large scale is difficult. The challenge is that the scale needed to prove its economic or therapeutic use is often forbiddingly expensive.

The preparatory work must therefore be very thorough, and secure support from leaders, and understand the usefulness of the new routine for the users of the application.

Make absolutely sure that the technology will work with the least possible disruption, and ease or benefit the healthcare personnel and patients involved.

9.6 Powys Teaching Local Health Board

Ensure that the marketplace is fully explored, and take into consideration the future technologies or modernisation agenda, ensuring that any solution is “future fit” and or interoperable with other healthcare systems.

Allow enough time to fully analyse, evaluate, procure, test and implement the solutions.

Research your options, taking into consideration clinical effectiveness as well as value for money.

Seek advice from others, including reference sites if available, and procurement colleagues.

9.7 Servicio Aragones de la Salud

A complete study of the existing tools should be made before adopting any solution. This deep analysis should include: economic (one-time, maintenance, licenses per user); usability (professionals, users, technical and administrative staff); interoperability; safety and security; user acceptance; clinical effectiveness; flexibility; performance; use of standards; renovated interfaces; responsive design; and use of non-obsolete technologies.

9.8 Servicio Vasco de Salud Osakidetza

Ensure that the procured service is appropriate from the clinical point of view (scientific validity), and the workflows are aligned with routine practice.

The procured service has to be attractive, user-friendly and straightforward for ease of handling.

The cCBT service has to be (ideally) integrated with the EHR so that all healthcare professionals can access the information gathered.

9.9 Badalona Serveis Assistencials

After an analysis of existing programmes, and if it is possible, the cheapest way to implement cCBT treatment is through developing your own programme. It is better than paying licences, and could even mean that your programme is tailored to your culture, and therefore it could be easier to implement in your region or area.

A better and more complete programme is achieved by sharing knowledge and experiences and, of course, sharing resources means saving development costs.

Be sure that the tool acquired allows you a bigger configuration, because a non-technical person (with the appropriate training) may able to create, generate and manage the programme, making the process easier and avoiding extra costs.

9.10 Conselleria de Sanidade de Galicia

Encourage an adequate and effective coordination among those in charge of the project, where roles are well defined and the action plan is realistic and organised.

Know the practical reality of the patients and professionals this project is addressed to; determine their needs and priorities, and adapt the project to them.

Achieve a quick and effective response to incidents and problems that may arise in the development of the project.

9.11 Azienda Unita Locale Socio Sanitaria N 9 di Treviso

Three main recommendations for a good procurement/acquirement process are:

- Define with EAAD a detailed and agreed contract regarding the terms and condition of use of the “iFightDepression” solution.
- Consider the availability of a budget specifically dedicated to this acquisition.
- Make available a person responsible to deal with local problems in the technical use of the tool. In addition to the support provided by EAAD, this was essential for our region to deal with problems more quickly.

9.12 Azienda Sanitaria Locale TO3

Select a validated and user friendly CCBT programme and/or ccVC system.

Promot a stepped care programme of MENTAL HEALTH, with low intensity treatments from the primary care level to more specialised treatment.

Give clinical support to patients from psychologists for the low intensity services.

Give technological support to patients using telehealth services.

Provide financing for human and material resources (space and time) for the low-intensity services and telehealth services.

Provide financing to improve the collaborative care through educational meeting with different professionals to increase collaborative care and international guidelines (NICE).

Organisational issues: every change in the organisational needs reinforcement and time to be accepted by people; more time, educational activities and reinforcement is very important for the implementation of new services , especially telehealth ones.

Give more attention to evidence based therapies to implement mental health services.

9.13 Middle East Technical University

The current state of cCBT in Turkey and context prevent further securitisation on the topic.

9.14 Tallinna Tehnikaulikool

A program has to be evidence-based, with a proof from many RCT studies.

A design should be flexible, interactive, user-friendly and with a logical structure.

Any cCBT service should engage professionals with patients, allowing them to chat and send feedback in real time as well.

10 Overall conclusions from the sites

Although the sites vary largely in culture, infrastructure and choice of cCBT solutions, some general findings can be drawn:

The legal considerations are divided into patient data protection issues, the need for a fair tender process, liability if contracts are not met, and copyright clarifications. As this field is developing, there are differences in programme clinical requirements between the sites.

The important key findings can be summarised under important headings:

- Technical: the software should be well tested, easy to apply, preferably standardised, and able to at least interface with the local EPR.
- Administrative: approval and legal procedures take a long time.
- Leadership: Support from leaders, clear goals, understanding of the role of cCBT in the healthcare.
- Acceptance and training of health professionals: Fitting the new therapeutic process into routine care is difficult and take time and training; understanding how to use the possibilities is a major challenge.
- Funding: Sufficient funding and willingness to wait for thorough cost benefit evaluation.

The recommendations from the sites can be grouped in the following main themes:

- Enough time: Implementation is a very complex undertaking that takes time, because it is an integration of the technical, organisational, educational and economical elements described above. Therefore enough time (years) must be allocated.
- Work together: The MasterMind project has demonstrated the value of working together.
- Get leadership backing: In a complex implementation process, it is important to get strong support and understanding from leaders.
- Make sure you have the right expertise: Both technical, organisational and professional expertise must work together right from the start of the implementation process.
- Inform properly about the implementation process and the tools available: This is equally important both for professionals and the general public.
- Evaluation: Evaluation of the cost benefit of the endeavour should be built into the project from the start, and as far as possible be a part of the normal running of cCBT.
- Technical and professional back up, support and advice when needed: When integrating cCBT into normal busy and demanding healthcare, support must be available as needed to prevent wear and disillusionment among patients and professionals.

Appendix A: Checklist for use ahead of procurement

This short checklist may be useful

During the preoperational stages, we recommend that the MAST protocol is studied and used as a first preparatory consideration ahead of procurement of cCBT applications.

The MAST protocol highlights the following important considerations ahead of procurements:

- Purpose of the telemedicine application?
- Relevant alternatives?
- International, national, regional or local level of assessment?
- Maturity of the application?
- Functions

The list below is an elaboration of the MAST protocol. The list is focused on procurement and implementation of cCBT, and is based our experiences from the MasterMind project.

The list is meant to be used in conjunction with the full text of D3.7. We recommend that any group planning to use cCBT in their healthcare work through the list. The list will serve as a reminder to cover important considerations ahead of procurement and implementation of cCBT. We recommend that the list be used in meetings where all relevant parties are present at the same time, and that the first meeting take place well ahead of any decisions on procurement.

What is the scientific documentation?

CCBT
- CBT principles.
- Programs
- Self-help
- Blended care
- Number of sessions

Technical platform
- Mode of delivery
- Mode of patient contact

How will cCBT be used?
- Pure self-help
- Blended care
  - Assisted self-help
  - Guided self-help
  - Integrated with other therapies
  - Stepped care

How will we get the cCBT application?
- Licensing
  - Price (per user? licensing for a period?)

- Make own
  - Alone
  - With others
  - Modify existing programs

How should the cCBT application be integrated into the existing health care platform?

- No integration
- Partial integration
- Full integration with EPR

What is the internet literacy and availability?

- Who can use internet?
- Is the technology infrastructure sufficient?

Operating cost and technological stability

- Start up
- Running cost independent of number users
- Cost depending on number of users

Do we have the staffing needed?

- Clinical staff
  - What type how many
- Technical staff

Evaluation of the cost benefit of cCBT at our site.

- Clinical effectiveness
- Patient satisfaction
- Usability
- Professionals' satisfaction
- Added value (management of alarms, integration with EHR)
- Flexibility of the solution
- Roles configuration
- Need for administration
- Ease to scale
- Adaptability to organisation (and not the other way around)
- Need for technological support
- Safety
- Use of standards

Legal considerations

- Procurement
  - EU legislation
  - National legislation
  - Licence conditions
  - Breach of contract
  - Tenure
- Privacy and data protection
  - EU regulations
  - National regulations

What is our estimation of the time needed to?

- prepare the legal documents and get them approved (licence, secure data storage and patient dossier protection,
- get the application
- integrate the application in our platform
- get staff
- train staff
- recruit patients
- evaluate the cCBT when it is in use
- allow generously for unforeseen events