Deliverable D6.3

Intermediate Trial Report 2nd Wave (cCBT)

MASTERMIND
“MAnagement of mental health diSorders Through advancEd technology and seRvices – telehealth for the MIND”
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AUTHORS: Ane Fullaondo (KRONIKGUNE) Olatz Albaina (KRONIKGUNE) Christiaan Vis (VU) Anne Etzelmuller (SCHOEN)

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Executive Summary

This document collects and documents the status of recruitment, the organisation description, and the information for the MAST domains regarding the execution of the cCBT intervention process of second wavers (Wales, Aragón, Basque Country, Badalona, Galicia, Piemonte, Treviso, Turkey, and Estonia).

In addition, this document also includes some of the barriers encountered by each pilot site that have caused problems during deployment of the service. Bringing the potential barriers to light facilitates the definition of contingency actions in advance and enhancement of weak aspects of the intervention.
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1. Introduction

1.1 Purpose of this document

This document contains the intermediate trial report for WP6 Internet based guided cCBT for treatment of depression-2nd wave (cCBT) in the MasterMind project. It uses the approach based on the MAST methodology.

The 2nd wave sites are:

- Powys teaching Local Health Board (PHB), Wales.
- Azienda Unità Locale Socio Sanitaria N9 di Treviso (ULSS9), Veneto, Italy.
- Azienda Sanitaria Locale TO3 (ASLTO3), Piemonte, Italy.
- Tallinna Tehnikaülikool (TUT), Estonia.
- Middle East Technical University (METU), Turkey.
- Servicio Aragónés de Salud (SALUD), Spain.
- Badalona Serveis Assistencials SA (BSA), Spain.
- Conselleria de Sanidade de Galicia (SERGAS), Spain.
- Servicio Vasco de Salud (OSAKIDETZA), Spain.

The MasterMind project aims to make high quality treatment for depression more widely available for adults suffering from the illness through the use of ICT. A major cause of morbidity worldwide, depression is characterised by its high incidence, social cost and the proven clinical effectiveness of ICT in its treatment.

The goal is to assess through implementation at scale (more than 5,000 patient overall, 2,300 patients in WP6) the impact of cCBT (computerised Cognitive Behavioural Therapy) and video conference for collaborative care (ccVC) on the treatment for depression across ten EU and Associated Countries (ten WP6 partners).

WP6 aims to:

1. Deploy at scale cCBT services for depressed adults across a number of EU and associated countries in regions where cCBT has been already piloted.
2. Collect the values of the indicators specified by the trial protocol before, during and after the trials (see deliverable D3.1).
3. Identify issues that can impede and enable implementation.
4. Devise ways to overcome the impeding factors and exploit the enabling factors.

The intermediate trial report for WP6 reports on the progress of the WP from month 1 to 25. The intermediate trial report gives an overview of preliminary results and sets the structure for the final report. This report only contains the information available; it does not report on any of the qualitative data that will be collected at the end of the trial.

The inclusion period started in September 2015 and is expected to end at the end of August 2016.
The three Intermediate Trial Reports, D5.3, D6.3 and D7.4, adopt the same structure and share part of the descriptive content, some of which has been included in other deliverables, e.g. D3.1 Scientific Trial Protocol. This approach has been chosen to ensure both readability (avoiding too many references to other documents) and that the deliverables can be read independently from each other.

1.2 Structure of document

Section 2 contains a description of the organisation of the project and the expected analysis.

Section 3 describes the status of recruitment.

Section 4 contains information for MAST Domain 1: Health problem and characteristics of the application.

Section 5 contains information for MAST Domain 2 and 3: Safety and clinical effectiveness.

Section 6 contains information for MAST Domain 4: Patient and healthcare professional perspectives.

Section 7 contains information for MAST Domain 5: Economic aspects.

Section 8 contains information for MAST Domain 6: Organisational aspects.

Section 9 contains information for MAST Domain 7: Socio-cultural, ethical and legal aspects.

Section 10 contains information on transferability assessment.

Section 11 contains information on lessons learned and recommendations.

Section 12 contains information on conclusions.

Appendix A gives the project objectives.

1.3 Glossary

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<td>Azienda Sanita Locale TO3</td>
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<tr>
<td>BDI</td>
<td>Beck Depression Inventory</td>
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<tr>
<td>BMP</td>
<td>Business Process Modelling</td>
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<td>BSA</td>
<td>Badalona</td>
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<tr>
<td>BTB</td>
<td>Beating The Blues</td>
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<tr>
<td>cCBT</td>
<td>Computerised Cognitive Behavioural Therapy</td>
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<tr>
<td>ccVC</td>
<td>Collaborative care Videoconference</td>
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<td>CSM</td>
<td>Centro di Salute Mentale</td>
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<td>DSM</td>
<td>Diagnostic and Statistical Manual of Mental Disorders</td>
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<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>EHR</td>
<td>Electronic Health Record</td>
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<td>FTE</td>
<td>Full Time Equivalent</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
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<tr>
<td>GPS</td>
<td>Global Positioning System</td>
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<tr>
<td>HIE</td>
<td>Health Information Exchange</td>
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<tr>
<td>HIS</td>
<td>Hospital Information System</td>
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<tr>
<td>IBM</td>
<td>International Business Machines</td>
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<tr>
<td>ICT</td>
<td>Information and Communication Technology</td>
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<tr>
<td>IMSP</td>
<td>Institut Municipal de Serveis Personals</td>
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<tr>
<td>LHA</td>
<td>Local Health Authority</td>
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<tr>
<td>MAST</td>
<td>Model for ASessment of Telemedicine</td>
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<tr>
<td>METU</td>
<td>Middle East technical University</td>
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<tr>
<td>MHCE</td>
<td>Mental Health Care Environment</td>
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<tr>
<td>MHCU</td>
<td>Mental Health Care Unit</td>
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<tr>
<td>MHD</td>
<td>Mental Health Department</td>
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<tr>
<td>OMI</td>
<td>Oficina Médica Informatizada</td>
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<tr>
<td>PACS</td>
<td>Picture Archiving and Communication System</td>
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<tr>
<td>PHB</td>
<td>Powys Health Board</td>
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<tr>
<td>PHQ</td>
<td>Patient Health Questionnaire</td>
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<tr>
<td>RIS</td>
<td>Radiology Information System</td>
</tr>
<tr>
<td>TUT</td>
<td>Tallinna Tehnikaülikool (Tallinn Technical University)</td>
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<tr>
<td>ULSS9</td>
<td>Unita Locale Socio Sanitaria</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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2. Methodology

The methodology is described in detail in the public deliverable D3.1 Scientific Study Protocol. An overview of the study design and data analysis plan is provided below.

2.1 Study design

To evaluate the 15 implementation projects, a multi-level and mixed-methods assessment will be undertaken using a process and pre-trial-post-trial study design. The evaluation will assess the viewpoints of three levels of stakeholders involved in the implementation projects: 1) patients, 2) healthcare professionals and 3) mental healthcare organisations. A mixed-methods approach will be employed which can provide a good understanding of what the implementation projects have achieved (quantitative results), and how or why these outcomes occurred (qualitative results). Using qualitative methods of data collection can also provide a good insight into unintended consequences, and will provide lessons for improvement of both interventions and the implementation, and up scaling of future interventions in routine practice.

The evaluation is structured according to the Model for ASessment of Telemedicine (MAST) in which seven highly interrelated domains will be assessed:

1) Client and care profiles.
2) Safety of patients.
3) Clinical change in depressive symptoms.
4) Implementation related costs.
5) Patient and professional perspectives towards cCBT and ccVC.
6) Organisational aspects and the broader
7) Social, legal and ethical issues related to employing cCBT and ccVC in routine practice.

Transferability will be assessed in two steps: first, experienced regions will implement cCBT in routine practice; the lessons learned from this first implementation wave will be employed by less experienced regions in a second wave.

Routine practice is our laboratory, thus the measurements should not interfere with the object of our study. Therefore, the study outcomes will be based on data already available in routine care, such as information on the reduction of depressive symptoms. In addition, short self-report questionnaires will be used to measure satisfaction with and usability of cCBT and ccVC, as this information is not available in routine focus group interviews with a limited group of healthcare professionals; structured interviews with representatives from the involved healthcare organisations will be undertaken to gain a better understanding of the process that leads to implementation success or failure.

The primary focal points of interest are reach, clinical effect, acceptability, appropriateness, implementation costs, and sustainability of the interventions in practice.

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1 Vis et al. 2015. Implementing and up-scaling evidence-based eMental health in Europe: The study protocol for the MasterMind project

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The resulting summative evaluation will provide valuable insights into the factors that influence the implementation and up-scaling of cCBT and ccVC in a variety of real political, social, economic and clinical contexts. It will provide insights into the perspectives of involved stakeholders, and result in concrete recommendations for implementing and up-scaling cCBT and ccVC for depression in different mental healthcare contexts.

2.2 Data management

To ensure a proper and timely statistical analysis of the collected data, it is essential that each pilot site in the study previously assures the correct entry of all requested data, including all relevant quality control. That way we will be able to carry out the data analysis as described in the next section within the time schedule and deadlines established in the project and by the European Commission.

Each pilot site in the study should ensure the quality of the data collected and its completeness, with sufficient controls to prevent the introduction of erroneous data and to ensure the complete confidentiality of patient information entered into the database. To do so, each pilot site has nominated a data manager.

Each pilot site uploads or exports their data to the central database on a monthly basis. Here, the most relevant aspects to be checked are:

- The number of valid participants included in the database.
- The quality of the information entered (completeness, no missing or erroneous data), mainly in relation to the most relevant variables of the study.
- Detect possible adverse effects of the intervention (mainly suicide attempts or worsening of the patient’s condition).

If any important mistake occurs, pilot sites have to communicate this to the coordination team.

In addition to the quality assurance carried out by pilot sites, Arsenal.IT (which is responsible for the central database) will check if the data uploaded are in the correct format according to the codebook, i.e. all mandatory indicators are entered, no incorrect symbols are introduced, ranges of the indicators are respected.

As a third layer of quality assurance, the evaluation team led by the scientific coordinators will monitor whether the data is of good scientific quality, e.g. the option of “missing answer” is used as little as possible, and instruments are monitored to measure and provide data as intended.

Once data capture is completed, each pilot site should fully recheck the quality of the information entered; if any errors are detected in the data entry, or data is missing, they will correct it prior to the statistical analysis.

2.3 Analysis plan

In general, the analysis consists of the following three steps:

- **Step 1**: The three levels of patient-healthcare professional-organisation are assumed to be hierarchical and interdependent issuing covariance. Therefore, the data
analysis will be approached using, amongst others, multilevel (implementation site) repeated measures regression techniques. Univariate analysis will be used to investigate demographic and clinical variables associated with adherence.

- **Step 2**: Through thematic analysis, semantic units of meaning related to the study objectives will be identified inductively within the qualitative data, and then coded and included with the quantitative data in statistical analysis².

- **Step 3**: Analysis of combined data will be of a descriptive nature in order to preserve heterogeneity between levels and contexts of sites. This will be done by using narrative summaries in the form of simple descriptions and tables of disaggregated data³. Additionally, advanced statistical methods will be employed to investigate cross-sectional relationships between levels (patients, healthcare professionals and organisations), care settings and, if possible, specific intervention characteristics.

Data collected will be analysed for each site and level (patient, healthcare professional and organisation) separately, and subsequently pooled for a combined aggregated analysis.

At patient level, data of all participants will be included in the analyses when they are eligible and agree to receive treatment, regardless of whether the participant ends their participation as intended. The reason for this is that information on e.g. complete discontinuation of treatment or parts of the treatment provides valuable information on the effectiveness of the implementation programme. As the focus of this study is on implementation effectiveness, no data, or parts of the data missing, is core information for the outcomes. Therefore, no imputation techniques will be applied. Data from healthcare professionals and representatives of the healthcare providers will be included in the analysis when the participants provide their consent.

In line with the objectives of the study (included in Appendix A), a proposed statistical analysis would be as follows.

### 2.3.1 Univariate analysis

**a. Differences between groups**, when provided with cCBT and ccVC in routine practice, as in:

- objective #1: To identify the factors which promote or hinder the implementation of cCBT and ccVC for treating depression in routine practice;
- objective #4: patients’ safety in terms of their mental health; or
- objective #5: To assess the perceived satisfaction and perceived usability;

will be statistically answered through the following tests:

- Quantitative variables: Student’s t-test or nonparametric Wilcoxon test for Non-Normal distributed variables.
- Qualitative variables: Chi-squared or Fisher exact test

**b. Study of changes over time (baseline and final values)**, as in Objective 2: changes over time of patients’ depressive symptoms.

- Quantitative variables: Student’s t-test or nonparametric Wilcoxon test for non-normal distributed variables for paired data.

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² Braun & Clarke, 2006
³ Dixon-Woods, Agarwal, Jones, Young, & Sutton, 2005
• Qualitative variables: McNemar’s test for paired data.

c. Differences between sites for intervention group (baseline-final difference means)
• Qualitative variables: ANOVA test or nonparametric Kruskal-Wallis test for non-normal distributed variables.
• Qualitative variables: Chi-squared test

2.3.2 Multivariate analysis

For the multivariate analysis, generalised longitudinal mixed models (GLMM) will be employed. The repeated measurements for each patient, and also the hierarchical structure of data, with patients nested in sites, must be taken into account. Among possible adjusting covariate, age, sex, depression severity, other comorbidities and other possible confounding variables taken from the univariate analysis should be considered.

In general, in the case of continuous outcomes (such as study of changes over time of patients’ depressive symptoms by health related quality of life questionnaires), linear multivariate regression models will be employed. For dichotomous outcomes (such as “reach of the interventions”: yes or no), logistic multivariate regression will be used. In all global analysis, multilevel multivariate analysis will be performed taking into account all the pilot sites.

2.3.3 Cost analysis

The economic analysis will comprise two elements:

• an estimate of the implementation and establishment costs of the services across the consortium; and

• a cost-effectiveness analysis based on the cost of change in experienced depression symptoms.

These analyses will be carried out to answer objective #3: To assess the costs associated with implementation and large-scale uptake of cCBT and ccVC for treating depression in routine practice.

2.3.4 Qualitative analysis

The qualitative analysis aligns to a constructivist understanding of the factors that facilitate or hinder implementation by focusing on the opinions that groups of healthcare professionals and individuals in managerial positions hold towards implementing cCBT and ccVC. We do not set out to answer a specific hypothesis. In that sense, the aim is to describe the participants’ experiences of a certain event, which allows presenting the participants’ point of view and staying close to data4.

The qualitative data collection and analysis are planned for the end of the study. Full details on the qualitative studies can be found in the next version of deliverable D3.1 Scientific study protocols. Below is an overview of the various components in the collection and analysis of the qualitative data in MasterMind.

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4 Neergaard et al. 2009
The qualitative study addresses the perspective of healthcare professionals and healthcare organisations for the following MAST domains:

2. Economic aspects.
3. Perspectives towards cCBT and ccVC.
4. Organisational aspects.
5. Social, legal and ethical aspects.

Domain 1 health problem and Domain 3 clinical effect are addressed by quantitative methods (see above).

The qualitative study follows a two-stepped emerging design that steers the contents of the structuring themes. Focus group discussions will be conducted with healthcare professionals (both therapists / referrers and team leaders / managers) to obtain collective views on the identified themes for cCBT and ccVC. These views feed into the semi-structured interviews with representatives (with decision power, management) of the involved healthcare organisations. The interviews are aimed at obtaining the opinions of individuals related to the context they are operating in.

For data collection and analysis, a combination of inductive and deductive methods will be applied. The MAST framework\(^5\), Consolidated Framework for Implementation Research (CFIR)\(^6\), Measurements for Determining Innovation (MIDI)\(^7\), RE-AIM\(^8\) and the Normalisation Process Theory (NPT)\(^9\) is used to deductively inform the initial themes. These frameworks (MAST, CFIR, MIDI, RE-AIM) and theory (NPT) describe the items and issues one should take into account when considering, planning, executing and evaluating an implementation project. Through iterative testing of the items in a pilot study, saturation of themes will be achieved inductively. Purposive sampling is applied.

For each theme, a comprehensive set of replies will be developed to ensure comparability between the different regions; i.e. each focus group and interview needs to score the various replies by means of the scoring card.

Credibility and validity will be ensured through cross verification (i.e. triangulation) of the outcomes of the various methods. This takes place in three ways:

- For healthcare professionals (therapists / referrers): confirmative research of the CSQ-3 and SUS questionnaires that are administered to healthcare professionals.
- For healthcare professionals (team leaders): confirmative research of the CSQ-3 and SUS questionnaires that are administered to healthcare professionals.

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• Between healthcare professionals and healthcare organisations upper-level management: confirmative research through the focus groups with professionals and team leaders.

Preceding the focus-group interviews and semi-structured interviews, participants will be asked to complete a short questionnaire to obtain general information about the interviewees and to prepare them for the interviews.

The analysis will be performed at both local and aggregated level, guided by a codebook.

An analysis plan will be developed to guide the analysis of qualitative data at local level.

The analysis consists of three distinct steps.

2.3.4.1 Step 1: Quantified answering categories

Descriptive statistics will be used to analyse the categorised and quantified data that is obtained by relating the qualitative answers to the pre-determined answering categories.

2.3.4.2 Step 2: Thematic analysis

Through thematic analysis, semantic units of meaning related to the initially defined themes will be identified within the qualitative data, and then coded and included with the quantitative data in statistical analysis².

Thematic analysis will be applied to those themes that are not included in step 1 (or those of special interest to the researchers). Those parts of the focus group discussions / interviews addressing the themes of interest will be transcribed verbatim and translated into English.

The process of coding and categorisation of data is structured according to the following four steps:

1. The transcribed data should be read to obtain an overview of data and to identify recurrent themes.
2. The transcribed data should be reread and coded according to the themes identified in the first step.
3. All text sections that are coded similarly are categorised into general themes.
4. To ensure correct coding and categorisation, the data should be reviewed for coherence and reallocated if discrepancies were found.

2.3.4.3 Step 3: Narrative summaries

Analysis of combined data (i.e. at central level) will be of a descriptive nature in order to preserve heterogeneity between the levels and contexts of sites. For each (type of) interview, a table is constructed with the final categorisations from steps 1 and 2 above, a brief description of the findings, a description of the data collection process, and a description of the participants (numbers, gender, age, education etc.) is prepared and included in the database which facilitates the analysis at aggregated level.

The descriptions of findings, data collection processes and participants will be created by using narrative summaries in the form of simple descriptions and tables of disaggregated data³. Based on this, statistical methods will be employed to investigate cross-sectional
relationships between levels (patients, healthcare professionals and organisations), care settings, and, if possible, specific intervention characteristics.
3. Status of recruitment at month 25

3.1 Introduction

In total, 5,260 patients are to be included in the project covering both cCBT and ccVC. From these, 2,300 patients are to be included in WP6.

The inclusion period started in month 19 of the project; since then, a total of 397 (17.26%) patients have been recruited for the cCBT part of the MasterMind project. However, this report only presents the results obtained from the data analysis realised in month 24. Thus, 365 patients have analysed (Table 1), and 140 professionals.

The trials started more slowly than expected with regard to patient inclusion. Some of reasons relate to delays in integrating cCBT programmes in organisations’ ICT corporate systems (e.g. Basque Country and Galicia), the high number of patient drop-outs (e.g. Wales and Estonia), or the problems of the collaboration of the health professionals involved in the study (e.g. Piemonte, Wales and Estonia).

Note that in some cases these data do not reflect the real situation of the trial sites. For example in Osakidetza, there are more than 110 patients recruited, but, due to incomplete information, it was not possible to upload the data to the central database.

As a consequence, new strategies have been adopted by the sites in order to solve these problems. Some of the solutions adopted are related to the inclusion of more professionals in the study (e.g. Aragon, Sergas, Basque Country, Badalona, Estonia and Piemonte) and to the development of more dissemination activities (e.g. Badalona, Estonia and Basque Country).

With these measures, it is expected that the healthcare professional and patient inclusion number will increase at most of the sites.

3.2 Recruitment status

Table 1: Recruitment status

<table>
<thead>
<tr>
<th></th>
<th>Wales</th>
<th>SP</th>
<th>IT</th>
<th>TR</th>
<th>EE</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PHB-IRH</td>
<td>SALUD</td>
<td>Osakidetza</td>
<td>BSA</td>
<td>SERGAS</td>
<td>ASLTO3</td>
</tr>
<tr>
<td>Number patients</td>
<td>161/500 (32%)</td>
<td>10/100 (10%)</td>
<td>24/300 (8%)</td>
<td>47/200 (23.5%)</td>
<td>0/200</td>
<td>86/300 (28.6%)</td>
</tr>
<tr>
<td>included (% of target)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number patients</td>
<td>161 (32%)</td>
<td>10 (10%)</td>
<td>10 (3.3%)</td>
<td>41 (20.5%)</td>
<td>0</td>
<td>75 (25%)</td>
</tr>
<tr>
<td>included in the data</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>analysis (% of target)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of healthcare</td>
<td>21/10 (210%)</td>
<td>4/2 (200%)</td>
<td>50/6 (833%)</td>
<td>40/4 (100%)</td>
<td>85/4 (2125%)</td>
<td>24/6 (400%)</td>
</tr>
<tr>
<td>professionals included (% of target)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of healthcare</td>
<td>4/1 (400%)</td>
<td>1/1 (100%)</td>
<td>9/3 (300%)</td>
<td>2/1 (200%)</td>
<td>1/1 (100%)</td>
<td>1/1 (100%)</td>
</tr>
<tr>
<td>organisations included (% of target)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Problem encountered

<table>
<thead>
<tr>
<th>PHB-IRH</th>
<th>Corrective action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Initial resistance from healthcare professionals.</td>
<td>1. Worked on building rapport with the HCPs and ensuring they were aware of the positive outcomes that could be achieved from this project.</td>
</tr>
<tr>
<td>2. High number of patient drop-outs.</td>
<td>2. Look at reasons as to why there are such a large number of drop-outs and establish ways to encourage engagement.</td>
</tr>
<tr>
<td>3. Restrictions on the use Beating the Blues software on modern technology – program cannot run on iPads, tablets or smartphones.</td>
<td>3. Laptops / desktops have been set up at community sites for patients who do not have access to this equipment at home. Look at software to make it more compatible as part of service development.</td>
</tr>
<tr>
<td>4. Decrease in referrals.</td>
<td>4. There has been a reduction in referrals, possibly due to the high number of drop-outs; therefore HCPs are not seeing the benefits anticipated. Further engagement required, as well as implementing programme into other service areas, i.e. GPs and secondary care.</td>
</tr>
</tbody>
</table>

## SALUD

| 1. Internal changes that affected the role of the professionals at the Mental Healthcare Unit (mainly changes of location and of responsibilities). | 1. Continuous collaboration with the professionals who participated at the beginning in the design of the pilot at their new locations, and training of the new professionals. |
| 2. High workload of the professionals at the Mental Healthcare Unit. | 2. Transfer of some of the tasks & responsibilities related to the programme (bureaucracy, training and patient follow up) from the psychiatrists to the nurses at the Mental Healthcare Unit. |
| 3. Low adherence to treatment.                         | 3. Change in the recruitment strategies (more focus on Primary Care) and in the follow-up of patient: more training materials; change from the un/self-guided approach to “medium” guidance; inclusion of face-to-face visits during treatment; one training session at the beginning.  
In order to reduce the number of drop-outs, a more guided treatment protocol was designed. It includes a training session by a nurse, then follow up (first by email and after by phone) and a face-to-face visit in the middle of the treatment. The number of logins to the platform and the number of sessions so far show that the changes have been effective, and adherence is now better. |

## OSAKIDETZA

| 1. Delays with Integration of the content of the cCBT programme into the corporate technological platform, since a collaboration agreement between the technical partner and Osakidetza was required to regulate the terms of use. | 1. The agreement has been signed, so the adaptation of the platform was finished in January.  
Currently, the technical team are working on installing improvements to the application. |
| 2. Low engagement of professionals.                    | 2. The engagement of professionals has been done by organising meetings in each centre. After this, they were asked to participate in the project; those clinicians interested have been registered for further training on the cCBT and ccVC protocol and diagnosis and treatment tools comprised in the protocol.  
In order to improve the engagement of professional, more disseminations meeting have been organised. |
## Problem encountered

<table>
<thead>
<tr>
<th>Problem encountered</th>
<th>Corrective action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BSA</strong></td>
<td></td>
</tr>
<tr>
<td>1. We have detected some cases in which users have not received the username and password to access the platform after recruitment, because the first email is sometimes marked as spam. At the moment, the web server running the cCBT platform has a self-signed certificate to ensure SSL communication. Some email clients consider those certificates not valid, and emails sent through them as possible harmful content; so they send the email to the spam folder.</td>
<td>1. Our technical team is looking forward to install a valid certificate on the web server, and not a self-signed one but from a trustworthy certificate entity. We have also improved the documentation provided to the care recipient in order to tackle such an issue.</td>
</tr>
<tr>
<td>2. Minor delays within the recruitment process, due to overloaded GPs.</td>
<td>2. New strategies improve these results have been:</td>
</tr>
<tr>
<td></td>
<td>a. We have taken advantage of the dissemination material from the first wave, and improved it with new dissemination actions through our communication channels (intranet, website, international website, Twitter, newsletter, posters...), by meetings through our Health Boards, which involved almost every organisation in our Community setting, and with specific local organisations devoted to mental health.</td>
</tr>
<tr>
<td></td>
<td>b. We have done more dissemination actions. For example, we have made videos to summarise the interaction from professional point of view, and the same with users' perspective.</td>
</tr>
<tr>
<td></td>
<td>c. We have decided to allocate some economic resources to those who recruit patients. Those resources are given to the Primary Care Centre and managed by the clinical chief. These resources can only be used for mentoring purposes.</td>
</tr>
<tr>
<td></td>
<td>d. We have performed one extra mentoring session per centre.</td>
</tr>
<tr>
<td></td>
<td>e. The project has been selected as a strategic one for the Medical Direction; the software platform will be integrated with the Personal Health Folder of Catalonia (which is accessible by every Catalan citizen). The idea is to improve accessibility for users through a single point of access for every single health resource available.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3. GPs are not able to follow-up on patients properly</td>
<td>3. We have included primary care nurses in order to follow-up on patients after inclusion by the GPs. GPs will only take over in case of a major exacerbation.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SERGAS</strong></td>
<td></td>
</tr>
<tr>
<td>1. Delays in cCBT implementation: Delays in cCBT implementation due to the organisation's decision to integrate cCBT in the new Electronic Health Record. This allows connection to the same data and tools for all healthcare professionals in SERGAS, and resolves ethic and legal problems in managing clinical data from patients.</td>
<td>1. Delay in the integration in the SERGAS computerised clinical history. The Internet platforms will include a web-based interface providing patients with access to cCBT therapy modules, a digital workbook, and a secure communication channel for both therapists and patients. The programme would be included in a computer-based clinical process that guides professionals in treating depression. In that process, professionals can assign that type of therapy to any patient.</td>
</tr>
<tr>
<td></td>
<td>All the interventions are registered in the electronic clinical record.</td>
</tr>
</tbody>
</table>
### Problem encountered vs Corrective action

<table>
<thead>
<tr>
<th>Problem encountered</th>
<th>Corrective action</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Professionals’ engagement: Recruitment has been suspended until the cCBT programme is finished, because the tool had been offered to all GPs in SERGAS, but not all the health centres. Inclusion will continue once the cCBT programme is finished.</td>
<td>2. Measures to improve professionals’ engagement: In order to improve the recruitment of professionals, the possibility of including psychiatrist and patients from specialised care is being evaluated. The selection and engagement of professionals in cCBT has been performed. Five accredited courses in CBT have been organised. The courses were taught by a psychologist with experience in CBT. In these courses, GPs were informed of the future integration of the CBT programme in the clinical history, and the possibility to offer it as a therapeutic tool. 80 GPs were selected to be involved in the project.</td>
</tr>
<tr>
<td>3. Professionals' drop-outs: Some GP drop-outs were expected because no every clinician pre-selected will have access to the cCBT programme due to the limitation of the hardware integration during the study.</td>
<td>3. Measures to avoid professionals' drop-outs: In order to avoid drop-outs due to technical problems and to maintain GP enthusiastic with the project, they decided to wait until the final programme is ready. They think that this will facilitate engagement. During 2015, other healthcare centres have been enrolled in the Mastermind project. Sergas is trying to offer a very helpful programme in order to provide better management of mild and moderate patients. In this way, Sergas has been able to enrol 49 more GPs. Once the final cCBT programme is integrated in the clinic history tool, they will start new courses in order to explain to participants the specific aspects of the protocol.</td>
</tr>
</tbody>
</table>

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### ASLTO3

1. Patients’ recruitment, and their degree of acceptance and/or skills for the innovative cCBT service (for the Italian context).

   - 1. In addition to the recruitment strategies previously described, in order to foster patients’ recruitment we are currently implementing the following actions.
     - Making it easier for GPs and psychiatrists to identify patients suitable for cCBT: our team is supporting their role from the very beginning, by taking care of the assessment and the administrative part.
     - Targeting potential patients in our territory who already have some expertise in using Internet, via posters, flyers, and a web campaign via Facebook, to allow the general population to know about the existence of project.
     - Including accredited psychiatric facilities in our territory as a possible source of patients.

2. Lack of a significant collaboration of all the health professionals involved throughout the entire pilot.

   - 2. Supporting on a weekly basis the GPs and psychiatrists involved, to help them to identify and overcome possible difficulties in recruiting patients for the pilot.

3. Not always an adequate Internet coverage throughout the entire territory of our unit.

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### ULS59

Some problems related to the engagement of clinicians have been encountered, and consequently in the enrolment of patients.

    - Mastermind team is creating a collaborative care culture with GPs and the different professionals of the Mental Health Centre. The most important corrective actions were: continuous training activities to make clinicians trained and engaged; and the support...
## Problem encountered

<table>
<thead>
<tr>
<th>METU</th>
<th>Corrective action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Delays during the initial management of collection of data for the codebook.</td>
<td>1. Decided to purchase an online data entry licence to collect survey data (Qualtrics). We encountered further delays to develop new data entry forms using Qualtrics, but now it is working very well.</td>
</tr>
<tr>
<td>2. Delays during generation of message templates to be received by patients. This delay was not expected, but we found that our message templates are incompatible with those of Alles under Controle.</td>
<td>2. We facilitated this process by generating responses from colleagues for made up problems which could be faced by university students. This way, we created message templates using a bottom-up approach rather than top-down approach. This is now finished.</td>
</tr>
</tbody>
</table>

Note that we have established protocols with patient referrals from student counselling services, to recruit directly from the waiting lists. We also have self-referral mechanisms.

## TUT

<table>
<thead>
<tr>
<th>1. Many patients are not eligible because of addictions, anxiety disorders and physical disabilities. Also, older patients have no computer skills to perform cCBT at home on their own.</th>
<th>1. More time is needed to recruit new patients.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. GPs who have started patients’ recruitment have less than 20 hours per week for appointments.</td>
<td>2. GPs need more time and more depressive patients to recruit them into the study. As a consequence, we are trying to involve psychologists. So, perhaps by promoting two different cCBT programmes we could increase the number of recruited patients.</td>
</tr>
<tr>
<td>3. Healthcare professionals are working part time.</td>
<td></td>
</tr>
</tbody>
</table>
4. Domain 1: Health problem and characteristics of the application

4.1 Introduction: what information is analysed in Domain 1

Domain 1 addresses the health problem and general characteristics of the patient, healthcare professional, and organisations involved. It results in a profile of the average patient, average healthcare professional, and organisation providing the services. The patient profiles will contain information on basic demographics (age, gender, education, employment, etc) and health status. The profiles of the healthcare professionals include demographic information, as well as professional experience in the field of mental healthcare and with the services. The organisational profiles include information in terms of age and size.

Data for this domain is mainly of a quantitative nature, and is used to answer the following questions from the project objectives: objective #1: To identify barriers and facilitators that influences the implementation of cCBT and ccVC for treating depression in routine practice; objective #6: To assess who receives cCBT and ccVC in routine practice; and objective #7: To assess the transferability of implementation and up scaling of cCBT and ccVC in routine practice in different care contexts. The instruments used to collect the data include Routine Outcome Measurements (ROM), the treatment platforms, and online questionnaires.

The quantitative data retrieved from the trial sites will be enriched with qualitative descriptions of the epidemiological health problem in the regions and an overview of the mental health systems currently active. This will enable drawing conclusions in terms of the reach of the implemented intervention for the given healthcare context.

4.2 Depressive disorder and its burden

Unipolar depressive disorder is currently one of the most prevalent mental disorders worldwide, and is predicted to be the number one overall cause of disability by 2030 for citizens of higher income countries\textsuperscript{10,11}. Depressive disorders can lead to reduced quality of life, impaired social and personal relationships, and disturbed professional life. They are often accompanied by other psychiatric disorders (e.g. anxiety disorders, substance abuse) and a variety of physical health problems. A depressive disorder may start early in life, and the course is often recurrent\textsuperscript{12,13,14}. Therefore, depressive disorders are associated with

\textsuperscript{10} mhGAP: Mental Health Gap Action Programme: scaling up care for mental, neurological and substance use disorders. World Health Organization, 2008;

\textsuperscript{11} Mathers C.D. & Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. Public Library of Science, 2006


\textsuperscript{14} Titov N. Current Opinion in Psychiatry. 2011.
substantial economic and societal costs, such as cost of treatment, loss of work productivity, absenteeism, early retirement, and premature death\textsuperscript{15,16,17}.

Despite the availability of effective treatments, the number of people that actually receive treatment for depressive disorders is not optimal. Care rates for adults with depression range from 35% to 45% in higher income countries\textsuperscript{18}. Suggested barriers that contribute to these low rates include: fear of or perceived stigmatisation\textsuperscript{19}; lack of adequately trained therapists; and the costs associated with healthcare delivery\textsuperscript{20}. Also, the often monodiagnostic nature of interventions available might limit treatment options for patients with mixed symptoms or the relatively high comorbidity among psychological disorders or interpersonal difficulties\textsuperscript{21}.

4.2.1 Burden within MasterMind trial sites

Table 2 below provides an estimate of the eligible patients within the local population of each trial site. The number of eligible patients is estimated by the prevalence of depression. Around 300,000 patients could be reached with the local cCBT programmes at this stage of the project. The local eligibility criteria for cCBT further limit the assumed notional reach of the local cCBT solutions.

Table 2: Estimate of eligible patients and description of local eligibility criteria

<table>
<thead>
<tr>
<th>Region</th>
<th>Number of eligible patients</th>
<th>Applicable (local) eligibility criteria for cCBT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wales: PHB-IRH</td>
<td>Information is not available; there does not seem to be a simple report in Wales that records this information.</td>
<td>- Suffers with mild to moderate depression and/or anxiety, including phobias and panics.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Has a willingness to be proactive in their treatment recovery and to use a computer-based programme.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Must have basic computer literacy.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Must not have suicidal ideas or plans.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Must be able to read/write English (reading age above 10/11 years).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Must not be in acute phase of psychosis or mania, or with cognitive function disorder i.e. dementia.</td>
</tr>
</tbody>
</table>


\textsuperscript{16} Wittchen et al. The size and burden of mental disorders and other disorders of the brain in Europe 2010. European Neuropsychopharmacology, 2011.

\textsuperscript{17} Gustavsson et al. Cost of disorders of the brain in Europe 2010. European Neuropsychopharmacology, 2011.

\textsuperscript{18} Andrews et al. 2001; Spijker et al. 2001

\textsuperscript{19} Hengartner:2012, VanVoorhees:2012

\textsuperscript{20} Kazdin & Blase 2011; Wittchen et al. 2011

\textsuperscript{21} Emmelkamp:2013, VanVoorhees:2012
### Region | Number of eligible patients | Applicable (local) eligibility criteria for cCBT
--- | --- | ---
Spain: SALUD | Prevalence of depression in Spain is 4% and in Aragón 3.6%. The population of the BHCA (Barbastro Healthcare Area) is 110,000 inhabitants, so around 4,000 people would be eligible to participate. | - Treated by the professionals recruited in MasterMind (belonging to the selected healthcare centres).
- Suffering from mild to moderate depression (PHQ-9 $\geq$ 10 and $\leq$ 20). Higher and lower scores in PHQ-9 are evaluated by the professional in charge of recruitment; depending on the patient, can be considered as eligible.
- No suicide ideation.
- Basic computer skills.
- Internet connection or location with it, so as to follow the programme.

Spain: Osakidetza | The Basque Country ended 2014 with a population of 2,188,985 people; the prevalence of depression is 5.3% in women and 1.8% for men. | Eligible patients for cCBT have been recruited according to the inclusion and exclusion criteria:
Inclusion criteria:
- 18 or older.
- Diagnosed of mild, moderate or severe depression (by means of the usual procedure to diagnose).
Exclusion criteria:
- Severe cognitive impairment (dementia or other mental disorders).
- Depression with psychotic features.
- Inability to use computers or mobile electronic devices.
- Insufficient command of spoken and written language.
- High suicide risk.
- In psychotherapy (taking antidepressants acceptable).

Spain: BSA | The prevalence for depression in Catalonia is 14.5%. According to the assigned population at primary care for BSA that would be around 15,950 eligible patients. | The main characteristics of the local eligibility criteria for cCBT in BSA are:
- Patients diagnosed by MDD (mild and moderate) by primary care.
- Patients that are able to manage and have access to technology.
- Patients should not be users of the Caring.me platform (previous project with similar characteristics as Mastermind).

Spain: SERGAS | 109,256 people in Galicia will suffer from depression. Total population 2.7 million habitants. | Inclusion criteria:
- Patient with a diagnosis of major depressive disorder mild-moderate who ask for treatment in a general health centre.
Exclusion criteria:
- Age under 18.
- No technical access to the programme at home.
- Maintenance of psychotherapy treatment at the time of the study.

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22 European Study of the Epidemiology of Mental Disorders (ESEMed)
23 Data about prevalence in Aragón
(http://www.aragon.es/estaticos/GobiernoAragon/Departamentos/SanidadBienestarSocialFamilia/Sanidad/Profesionales/13_SaludPublica/17_Informacion_sobre_enfermedades/Ansiedad%20o%20depresi%C3%B3n.%20Informe%20O MIAP.%20Prevalencia%20a%2031_12_2012.pdf)
<table>
<thead>
<tr>
<th>Region</th>
<th>Number of eligible patients</th>
<th>Applicable (local) eligibility criteria for cCBT</th>
</tr>
</thead>
</table>
| Italy: ASLTO3 | N = 3,000 (0.5% of 600,000 inhabitants) | We expect to recruit adult patients of different ages, gender and variable level of formal education. More precisely, inclusion criteria are as follows:  
- Patients aged 18 or over.  
- Suffering from mild to moderate depression (as indicated by medical history, clinical interview, and the screening measure PHQ-9). Exclusion criteria are as follows:  
- At risk of committing suicide.  
- Absence of a computer (or other electronic device) to use the ccVC/cCBT tools. |
| Italy: ULSS9 | About 1,000 in total for the two district involved (LHA n. 9)\(^\text{24}\) and about 14,000 for the Veneto Region\(^\text{25}\) | Eligibility criteria:  
- Adult patients (18 or over)  
- Symptoms of mild, moderate or severe depression. |
| Turkey: METU | Prevalence of depression among university students is approximately 25% in Turkey\(^\text{26}\). We are recruiting from mainly METU and BU universities which have 26,500 and 15,500 students each. So the approximate number of students that are eligible is 10,250. We also have student population to be added from Germany, but prevalence from that population is unavailable at the moment. | Eligibility criteria:  
- Young Adults (18 - 30).  
- Suffering from mild to moderate depression (10 < BDI < 30).  
- Basic use of computer technology.  
- Easy access to Internet and familiarity with the use of email and online educational materials. Exclusion criteria:  
- Suicidal plans or projects. |
| Estonia: TUT | Study performed by Aluoja, et all (2004) emphasises the prevalence of 11.1% depressed people among population. Participants n = 4,711, aged 15-74. EST-Q was used, | Patients’ recruitment criteria:  
- Age: adults, 18+.  
- Clinical diagnosis according to ICD-10, DSM-IV.  
- No addictions (alcohol, nicotine), personal, disassociated, bipolar disorders or dementia (schizophrenia).  
- No physical disabilities.  
- No high risk of suicidality when in need of clinical intervention.  
- No patient who does not have possibility to perform or continue treatment process at home individually (lack of computers or computer skills). |

\(^{24}\) SISTE Local Information System  
\(^{25}\) http://www.regione.veneto.it/web/sanita/salute-mentale  
\(^{26}\) Binbay et.al, 2013
4.3 Current mental healthcare settings targeting depression

The majority of persons with a mild or moderate depressive disorder receive treatment in primary care settings, mostly from GPs, by means of antidepressants and less by brief psychotherapeutic interventions. Patients suffering from more severe depressive disorders are often referred to specialised mental healthcare services where treatment consists of medication, psychotherapy, or a combination of both\textsuperscript{27}. For specialised care, there is an overall trend in Europe to replace inpatient by outpatient care in specialised mental health centres, and treat depression if appropriate in the community in primary care settings. However, the rates differ considerably between EU countries.

In this sense, in all Mastermind deployment sites, patients with psychological problems receive most or all of their mental health care in primary care. The use of CBT resource could be a way to improve the delivery of psychological interventions in general practice. This would allow for short consultations and for the clinician to be a facilitator rather than a cognitive therapist. These features could improve feasibility in general practice, where the volume of patients is high, and it is essential that interventions are brief and practical.

4.3.1 PHB-IRH

The Mental Health Service is under huge pressure to deliver excellent service in times of financial challenge and diminishing resources. This often results in patients waiting long periods of time to be treated for depression. cCBT is recognised as a proven online treatment for depression. In Powys, this could reduce these issues through earlier intervention resulting in service improvement.

The majority of the persons suffering with mild/moderate depression first contact their GP; the GP would usually undertake watchful waiting or possible treatment with antidepressants. If this was not successful, then the GP would refer the patient into the Local Primary Mental Health Support Service (LPMHSS) for further assessment and psychological therapy.

4.3.2 SALUD

The primary care professionals at the Primary Care Centres have the first and closest contact with the patients. They do the first diagnosis, and normally treat mild to moderate depression. This treatment might include an anti-depressants prescription. When there is a patient profile with more complex needs and/or the symptoms are more severe, the GP might decide whether to contact the Mental HealthCare Unit at the main general hospital or not. The frequency and the type of interaction depends very much on the GP workload and on his/her training and experience in the treatment of mental health disorders. These contacts with the Mental Healthcare Unit can be of two types:

- Consultations. This kind of contact normally consists of a description of a case with specific questions about diagnosis or therapeutic treatment. This is now one of the processes which are being assessed in the ccVC pilot in MasterMind.
- Direct referral, when the severity or the complexity of the patient profile indicates specialised treatment.

\textsuperscript{27} Cuijpers et al., 2012; Cuijpers, van Straten, Andersson, & van Oppen, 2008b; Wittchen et al., 2011
4.3.3 OSAKIDETZA

The Basque Health System includes 14 hospitals, more than 100 primary care clinics organised through three different geographical areas, apart from the Mental Health Centres, Emergencies and Basque Transfusions and Human Tissue Centre. More than 30,000 professionals work for Osaikidetza, which could be considered the biggest organisation of the Basque Country.

Mental health services in the Basque Country are based on the community care model which:

(i) promotes integration and standardisation of mental health care services;

(ii) gives support and facilitates social integration and normalisation of the affected population; and

(iii) endorses coordination of social and health care.

Mental health services consist of three regional networks with four psychiatric hospitals (777 beds), two contracted long-term mental hospitals, and several mental health centres in close collaboration with primary care. Mental health services in the Basque Country consist of departments and functions across the three provinces of the Autonomous Basque Community.

Service deployment in the Basque Country includes different actors with specific tasks: GPs from primary care, psychologists and psychiatrists from Mental Health Centres and/hospitals, managers and patients. Healthcare professionals belong to distinct organisations of the three provinces of the Basque Country. According to the organisational model defined, GPs are the main actors responsible for patient recruitment. They invite candidate patients, who meet the inclusion criteria defined in the general scientific trial protocol, to participate in MasterMind Project. In addition to these criteria, GPs will ensure that the patient is able to handle the online cCBT tool.

4.3.4 BSA

Badalona Serveis Assistencials (BSA) is a consortium that manages seven Primary Care Centres, an acute care hospital (“Hospital Municipal de Badalona”), an intermediate care hospital (“Centre Sociosanitari El Carme”), an integrated homecare service, and a Centre for Sexual and Reproductive Health. BSA provides care to a total population of 234,000 inhabitants in the most populated suburban area of Barcelona. BSA employs more than 1,200 people.

One of the most significant characteristics is the strategy based on the coordination of the different levels of care: from primary and home care to hospital care, all the interventions are well coordinated and globally supervised. This integrated model of care ensures the best service for citizens when and where needed, optimising the use of resources to guarantee the best overall care. The possibility of sharing the EHCER among the different healthcare levels allows the development of new models of care to improve the access of patients to secondary care, without generating duplications or delays in lab tests or other diagnostic procedures. This allows specialists to consult patient both at their home and in the Primary Care Centres.
We also work very closely with IMSP (in Catalan, Institut Municipal de Serveis Personals). It is a public organisation operating in Badalona region which is in charge of providing the most specialised mental care support. It is also owned by the City Council of Badalona.

4.3.5 SERGAS

Galicia is a territory with a significant demographic dispersion. The mental health services are designed from a community perspective in order to provide resources for the whole population.

Any health problem is evaluated first by a GP. In the case of mental illnesses, GPs treat the most prevalent and mild diseases such as adaptation problems or mild depression. GPs can refer to secondary care any case that he considers specifically psychosis or severe affective disorders. Mild and moderate depression cases are usually treated by the GP.

Secondary care depends of psychiatric services. There are seven psychiatric services in Galicia. Each of them has community based resources and hospital care units. The basic unit for community based approach is the Mental Health Unit (USM). Each of them is composed by a team of psychiatrist, psychologist and a nurse, plus a social worker. We also have continuity care teams, in order to treat the most isolated cases at their home. Chronic cases could be treated in Units for Psychosocial Rehabilitation or supervised flats.

There are also units in general hospitals for treating severe acute patients. We have two psychiatric hospitals for admissions of patients with very severe chronic conditions.

There are 52 Mental Health Units in Galicia. They are in general health centres or in hospitals. We are recruiting patients in three of the seven health areas of our region; all of them are part of a single health service (SERGAS). Six Mental Health Units have been selected to pilot the MMIND cCBT programme, and 11 general health centres for ccVC.

4.3.6 ASLTO3

ASLTO3, partner of the MasterMind project, is located in Piedmont, and covers the widest part of the regional territory, as compared to the other ASL. Overall, the psychiatric services of ASLTO3 treat about 9,000 cases per year. They receive about 3,000 new cases every year, with an estimated proportion of depressive disorders of around 20%. Over the years, a specific pathway has been developed for the assessment and treatment of people suffering from depression. This pathway encompasses an assessment stage of the patients in the Mental Health Outpatient Services (11 distributed in the territory of the ASLTO3) and, when appropriate, this is followed by referral to a therapeutic treatment of low, medium or high intensity, depending on the clinical needs of the patients. Patients can be treated in three hospitals (with 10 beds each for psychiatric emergencies, and an average length of stay of around 12 days), or in two private accredited facilities (with 140 beds in total, and an average length of stay of around 36 days).

In addition, in the territory covered by ASLTO3 there are currently more than 400 GPs who represent a precious resource. In the last years, collaboration of the GPs has increased the capacity for early detection of those who are suffering (or at risk of suffering) from depression. However, it is currently difficult to provide adequate therapeutic treatment to such a large number of patients with traditional approaches (e.g. face-to-face psychotherapy), especially as the number of patients with depressive disorders will increase significantly in the next decades (World Health Organization, 2001). Thus, the introduction
in the territory of ASL TO3 of a cCBT service and the increased use of video-conference system for clinical monitoring (as implied by the MasterMind pilot) would probably allow a significant proportion of patients with mild to moderate depression to benefit from a treatment of their disorder.

4.3.7 ULSS9

The Mental Health Department in Treviso is composed by two psychiatric services, one for 200,000 people and has two psychiatric wards and four Mental Health Centres, one for 100,000 people. Patients suffering from severe mental health disorders are often referred to these mental healthcare services where treatment consists of medication, psychotherapy, or a combination of both. The majority of persons with a mild or moderate mental disorder, depressive disorders included, receive treatment in primary care settings from GPs, mostly medication.

During the follow-up, the specialist (Mastermind psychologist and psychiatrist) meets the patient at the Mental Health Centre for evaluation, and considers the possibility of assigning for cCBT treatment, in collaboration with the GP by collaborative care through videoconference or phone. At the Mental Health Centre, depending on the clinical situation presented, the patient will be invited to start cCBT treatment or to start an adequate treatment for his condition, with or without medication. In both cases, the GP has the opportunity to share the patient status with the specialist, at any time, through videoconferencing with the specialist and in the shared Mastermind folder in the electronic system. The patient, who agrees to undergo cCBT treatment, will be adequately informed and invited to carry out the treatment activities, under the supervision of a psychiatrist mental health specialist or a case manager (MHC workers).

4.3.8 METU

The prevalence of depression in the general Turkish population is of the order of 13% in women and 8% in men according to Turkish psychiatry association. However, the prevalence is much higher among university students (25% according to Binbay et.al 2013). The target population of MasterMind in Turkey has been university students. For this purpose, several customisation procedures have been implemented. First of all, the language used in the cCBT modules is tilted towards the jargon common to youth; also the respect code in the language is tilted towards addressing younger people. Secondly, the therapists are chosen from among specialists closer to the patient populations; the therapists are graduates of psychology departments with MS degrees, they are licensed in CBT, and they are students themselves, pursuing PhD. Finally, the delivery of services is entirely free. The online service is based on the educational LMS platform offered by METU. The modules are entered as a part of a regular online class. If the service is licensed in the future, this can easily be done through METU.

Local patient recruitment was initially planned to be done only from the METU student counselling services, AYNA. But later, after a few encounters with other universities, Bogazici University’s BUREM also joined. Both of these services are overcrowded with student patients. Usually the time spent in the waiting list is around 5-6 months. The recruitment strategy takes patients from the waiting list, but keeps their place on the list, so that if the patients wish to continue with face-to-face therapy after cCBT, this is still available. One problem seems to be the creativity of students to have thoughts of suicide. This is an exclusion criteria, and it appears that quite a few students indicate that they have
developed a suicidal plan after they gave consent to participate. In these cases, they have to be immediately referred to face-to-face therapy, so they have to be dropped out of Top Sende. Currently remedies are being sought for this issue.

4.3.9 TUT

In Estonia, patients have an opportunity to choose whether they like to visit their GP in the primary healthcare setting, or to visit a psychologist / psychotherapist / psychiatrist in the mental health care centre without any referral letter; mental healthcare service is available also in private health care centres. The psychiatric services in the Register of Activity Licences of the Health Board are classified as follows:

- Outpatient psychiatric services.
- Outpatient children’s psychiatry services.
- Outpatient psychiatric services (including children’s psychiatry).
- Children’s psychiatry services.
- Psychiatric services of day medical treatment.
- Psychiatric services (including children’s psychiatry) inpatient psychiatric services.
- Auxiliary psychotherapy services.
- Out-patient psychotherapy.

74 natural or legal persons, providing health services, hold a valid activity licence for the provision of psychiatric services. Some of them provide services to mainly or only a certain target group (e.g. people suffering from mental disorders caused by the consumption of psychoactive substances, and to those suffering from sexual dysfunctions).

Social services, with reference to people with severe and long-lasting mental special needs, are provided by 86 service providers who provide the following services:

- Supported living.
- Living in a community.
- Supported employment.
- Supporting everyday life.
- 24-hour care.
- 24-hour care with intensified monitoring.

Outpatient psychiatric care

If possible, the removal of persons from familiar surroundings is avoided in the provision of psychiatric care. The percentage of outpatient psychiatric treatments is increasing in Estonia year by year. Private practices have developed vigorously, giving patients a better option. A more detailed description of the outpatient psychiatric care with inpatient psychiatric care is available in: http://ee.euro.who.int/mental_health_system.pdf.
Inpatient psychiatric care

Inpatient psychiatric care is provided as a community service in central and general hospitals. A more detailed description of the service is available in: http://ee.euro.who.int/mental_health_system.pdf

In the case of insured patients, the Health Insurance Fund pays for the inpatient psychiatric care. Patients not covered by health insurance pay themselves for the care provided. All persons in the territory of Estonia are provided with emergency inpatient psychiatric care (similar to other emergency care), and emergency care provided to a person not covered by health insurance is paid for out of the funds prescribed for such purpose in the state budget.

Psychiatric day care

Three healthcare institutions provide psychiatric day care service in Estonia. This is psychiatric care during the provision of which the patient is at the healthcare institution in the daytime only. In the case of insured patients, the Health Insurance Fund pays for the psychiatric day care service. Patients not covered by health insurance pay themselves for the care provided.

4.4 Interventions implemented in MasterMind

Within MasterMind, the participating healthcare organisations will implement evidence-based cCBT interventions in routine mental healthcare practice. The cCBT interventions are evidence-based, in that there is clinical evidence from randomised controlled trials demonstrating that the underlying therapeutic principles contribute to improvement of depressive symptoms and health related client outcomes.

The exact treatment and service modalities depend on the type and structure of the technical cCBT platform used, the individual needs of patients, and the actual care setting. For all implementation sites, the treatment protocols and technological solutions adhere to the multidisciplinary NICE clinical guidelines for depression developed by the National Institute for Care and Excellence in the UK. The core components of all cCBT treatments are: (1) psycho-education, (2) cognitive restructuring, (3) behavioural activation, and (4) relapse prevention. These components are delivered over a number of sessions, either online (with minimal guidance), or via a combination of face-to-face sessions with a mental healthcare professional, alternating with online sessions in which the CBT components are described and practised.

Patients for whom CBT treatment is indicated and have for example difficulty visiting the clinic will be offered a video supported cCBT treatment. The online sessions are delivered through a secure web-based online treatment platform. The internet platforms include a web-based interface providing patients with access to cCBT therapy modules, a digital workbook, and a secure communication channel for both therapists and patients.

The cCBT solutions adopted by 2nd wavers have followed a similar procedure in order to decide the cCBT programme used. In this way, some of the aspects that have been considered are in relation to the collection of information on the different characteristics of

28 NICE. Depression: the Treatment and Management of Depression in Adults. 2009.
the programmes such as structure and clinical content of the online therapy, costs, or privacy and confidentiality.

The following table shows the cCBT programmes chosen by 2nd wavers.

**Table 3: cCBT programmes chosen by 2nd wavers**

<table>
<thead>
<tr>
<th>Pilot site</th>
<th>cCBT programme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wales</td>
<td>Beating the Blues</td>
</tr>
<tr>
<td>Piemonte</td>
<td>iFight Depression</td>
</tr>
<tr>
<td>Treviso</td>
<td>iFight Depression</td>
</tr>
<tr>
<td>Estonia</td>
<td>iFight Depression</td>
</tr>
<tr>
<td>Turkey</td>
<td>Top Sende (a brand new programme in Turkish)</td>
</tr>
<tr>
<td>Badalona</td>
<td></td>
</tr>
<tr>
<td>Aragón</td>
<td>Supera tu depresión (adapted by Spanish cluster)</td>
</tr>
<tr>
<td>Galicia</td>
<td></td>
</tr>
<tr>
<td>Basque Country</td>
<td></td>
</tr>
</tbody>
</table>

### 4.4.1 PHB-IRH (Wales)

Powys had adopted the ‘Beating the Blues’ system of online CBT developed by Ultrasis (but now owned by 365 Health & Wellbeing). Beating the Blues is a cCBT programme for depression and anxiety. It is a clinically proven drug-free treatment that is cost effective and time efficient, which integrates best practice in psychological therapies with advanced multimedia software. The programme was developed and evaluated by Ultrasis in collaboration with a research team from the Institute of Psychiatry, Kings College, London, lead by Dr Judy Proudfoot. Beating the Blues has been evaluated through independent clinical trials, and the results published by the British Journal of Psychiatry.

The eight sessions enable users to identify specific problems and realistic treatment goals. Users work through cognitive modules to identify and challenge automatic thoughts, thinking errors, distractions, core beliefs and attributional styles. Problem directed behavioural components are interlinked with these cognitive elements, enabling users to work on activity scheduling, problem solving, graded exposure, task breakdown or sleep management according to their specific problems. The final session looks at action planning and relapse prevention.

Beating the Blues uses interactive modules, animations and voice-overs to motivate and engage the user. A major feature is a series of filmed case studies of fictional patients who model the symptoms of anxiety and depression, and help demonstrate the treatment by CBT.

The programme offers clinicians a remote monitoring tool whereby users complete modules from any computer, whilst their clinical helper can print off reports from their own system. The programme has integrated assessment tools PHQ9 and GAD 7 in line with IAPT requirements. Suicide risk alert emails are generated, and regular encouragement is fed back to users.
4.4.2 SALUD, OSAKIDETZA, BSA and SERGAS (Spain)

The four Spanish organisations participating in Mastermind agreed to adapt existing evidence-based cCBT programmes to their local cultural context. For this purpose, a group of healthcare professionals (psychiatrists and psychologists) from these regions with expertise in CBT interventions and on-line therapies directed to other pathologies, have worked together to define the clinical content of the cCBT programme to be implemented.

The adapted cCBT programme is called “Supera tu depresión” (Overcome your depression) and consists of eight modules:

1. What is depression?
   Description of depression, its main symptoms, and guidelines to face depression are stated. In addition, how to manage anxiety and relaxation techniques are explained.

2. How different activities affect our mood.
   Relationship between behaviour and emotions is explained, and how changing our daily activities can influence our mood.

3. Increasing pleasant activities. Additional information on healthy habits.
   Guidelines to plan and perform pleasant activities are given.

4. How our thoughts affect our mood.
   Relationship between thoughts and mood is defined, and different types of thoughts that boost the appearance of the depression are listed and illustrated with examples. In addition, guidelines to detect negative thoughts are given.

5. Learning to change our negative thoughts.
   Benefits of being optimistic are explained and how to reverse a negative thought into a more reasonable and positive idea.

6. Learning to change our negative thoughts. Special situations.
   Different techniques to boost positive thoughts are given, such as distraction, and a set of exercises is proposed.

7. Problem solving.
   Steps to problem solving are explained: 1) identification of the problem, 2) specification of the response that usually occurs, 3) listing alternative solutions, 4) assessment of consequences of each alternative solution, 5) analysis of the results.

8. Looking to the future.

4.4.2.1 Salud

The strategy in MasterMind also includes a "stepped approach", as there was no previous experience in the area / organisation in the use of cCBT nor in mental health technology-related projects. This stepped approach is composed of two routes of incremental activity:

- Beginning at the Mental Healthcare Unit with a few patients, and after that small intervention, inclusion of recruitment by a few GPs at some Healthcare Centres.
- The initial approach was to try a "self / auto-guided" intervention with a minimum follow-up. Monitoring would be increased / tailored depending on the effectiveness of the intervention and on the adherence to treatment from users.
The plan includes:

- A first phase with a few patients, in which psychiatrists from the Mental Health Care Unit would put the final touches to the intervention. This initial phase started in October 2015, and included a few patients recruited from the Mental Health Care Unit. The initial results of this small experience led to a redesign of the intervention due to the lack of adherence to treatment of patients, including more training materials, more technical support, and the inclusion of training sessions. Also, the complex profiles of patients at the Mental Health Care Unit caused some changes in the recruitment strategies.

- A second phase focused on recruitment at the Primary Care Centres. This phase started in February 2016 with the intervention of GPs to do the recruitment, and the nurses from primary care to do the follow-up. Recruitment at the Mental Health Care Unit also continues, but with a few changes from the initial approach (more collaboration with the Mental Health Care Nurses and a more intensive monitoring of patients).

Once the solution and the protocol are assessed and validated at these centres, further deployments are foreseen.

**4.4.2.2 Osakidetza**

Once the patient has accepted to participate in the intervention, the GP or the GP nurse is in charge of explaining how the online cCBT tools works. After the demo, the patient is given a username and a password and he/she can start with the first session scheduled in the cCBT programme. Before starting with the session, the patient will have to fill some questionnaires online (MANSA-2, PHQ-9, BDI and EuroQoL).

The Mastermind platform is a web application developed in HTML5. Access to this application is possible by mobile, tablet or PC. It is composed of two parts or "consoles":

- Patient console: accessible by link in the personal health folder, this console is used by two roles (patient and caregiver). Authentication in this console is supported by personal certificate or Barcode – Advanced electronic signature.
  - The most important functionalities provided are:
    - Empowerment of patients in your activities to check your disease.
    - Education about your disease.
    - To answer questionnaires about your health status or disease status.
    - To send messages to clinicians.

- Clinical Console: accessible by URL deployed in internal environment of public health service (Osakideza). It is accessible only by clinicians. The method for authentication is SSO (Single Sign On) using the user and password introduced by user in Osakidetza environment.
  - The most important functionalities are:
    - Management of the clinical contents of app (movies, questionnaires, educational documents...).
    - Monitoring patients' status.
    - Check alarms.
4.4.2.3 BSA

A platform recently developed through a joint venture with Arvato-Bertelsmann is used to deploy the cCBT service. The platform has now been integrated within BSA information systems. A positive aspect about the platform is that it has been designed in order to be able to change / tune the interventions to be deployed very easily by a non-programmer.

The platform is designed in order to be able to deploy any internet intervention, and has the following main components:

- **Workflow engine**: This defines and manages the flow of the intervention according to roles, tasks and time.
- **Content management system**: This manages the content which is shown by the intervention. The content can be: enriched text integrated in the web page; files to download; external content including videos.
- **Communication system**: This manages the communication channels and messages between the different roles involved within the interventions. The communication channels can be: internal messaging system, SMS and email.
- **Form/questionnaire tool**: This manages every questionnaire or form within the context of the platform. The questionnaires can be fully tuned according to the needs of the intervention.

4.4.2.4 SERGAS

The IT department has integrated the CBT programme in our electronic clinic report, and to ensure that the online sessions are delivered through a secure web-based online treatment platform. The internet platforms include a web-based interface providing patients with access to CBT therapy modules, a digital workbook, and a secure communication channel for both therapists and patients. The programme would be included in a computer-based clinical process that guides professionals in treating depression. In that process, professionals could assign that kind of therapy to any patient they consider.

All the interventions are registered in the electronic clinical report. This electronic clinical report has a special security profile in order to protect clinical data in accordance with Spanish legislation.

During 2016, other healthcare centres have been enrolled in the Mastermind project. We try to offer a very helpful programme in order to provide better management of mild and moderate patients. We have been able to enrol 49 GPs more during this time. Once we have the final cCBT programme integrated in our clinic history tool, we will start new courses in order to explain to participants the specific aspects of the protocol.

4.4.3 ASLTO3 and ULSS9 (Italy)

Both Italian partners have adopted the iFightDepression© system for online CBT. iFight Depression was developed within the project Predi-NU, Preventing depression and improving awareness through networking in the EU (http://www.predi-nu.eu/).

The iFightDepression tool is a guided, internet-based self-management programme for individuals experiencing mild to moderate depression, it was developed based on existing evidence, best practice recommendations, and user and expert consensus. The tool is free
to use, and is intended to help individuals to self-manage their symptoms of depression and to promote recovery, with support from a trained GP or mental health professional. The tool is based on the principles of CBT; it consists of six core modules, and three additional modules that can be performed by patients, according to their clinical needs. More precisely, iFightDepression tool consists of informative modules that focus on increasing daily activity, identifying and challenging unhelpful thought patterns, monitoring mood, adopting healthy sleeping patterns, and maintaining a healthy lifestyle. Associated worksheets and exercises encourage users of the tool to practise and consolidate new skills and to promote self-monitoring.

4.4.3.1 ASLTO3

After the inclusion of patients in the pilot, the MasterMind team contacts patients to provide the username to access the iFightDepression website, and to explain in more detail how to go through the website. The aim is to ensure that the patient gets the greatest possible benefits from the clinical tool. In addition, a guide on how to use the tool is included within the cCBT tool itself.

Patients receive support from the MasterMind team for the entire duration of the pilot. The team will be available via email or phone to support patients, and will also be in contact with patients’ GPs, to solve possible problems related to the clinical use of the tool. For technical needs, our technical MasterMind partner (CSI Piemonte) will be the first-line of intervention. In addition, help lines and contact details of emergency services are provided to all patients; they are also included in the appropriate contact section of the cCBT tool.

Our cCBT programme will be mainly delivered at patient's home. GPs, psychologists and psychiatrists are eligible to refer to the service. Health professionals are required to possess a PC, laptop or tablet to be able to use the tool and supervise patients’ treatment. If professionals are willing to participate, but do not have an electronic device available, it will be provided by our MasterMind team. A specific email account has been created through which health professionals can contact project staff, and through which information about the cCBT tool is sent.

4.4.4 METU (Turkey)

Metu has developed a new programme, Top Sende, based on two first wave CBT programmes, Alles under Controle and GetOn. This new programme contains six modules which are described in the table below:

<table>
<thead>
<tr>
<th>MODULE</th>
<th>DESCRIPTION</th>
<th>EXERCISE</th>
</tr>
</thead>
</table>
| 1      | Identification of important things and classification of problems | o List of important things.  
o List of problems and worries. |
| 2      | Behavioural activation | o List of enjoyable activities.  
o Planning of daily activities.  
o Diary. |
| 3      | Working on important and solvable problems | o Book keeping for an attempt to solve a single important problem. |
This is an approach rooted in problem solving therapy, augmented with behavioural activation. The computational backbone is the learning management system used in METU for online course management. It requires PC access and internet connection.

### 4.4.5 TUT (Estonia)

Estonia is using also iFightDepression programme, similarly to the Italian pilot sites. But, additionally, in Estonia a CBT Basic App has been created by clinical psychologist Mrs. Kärt Lust-Paal from Estonia, which is currently available as iOS version in the App Store. The modern design of this cCBT app makes the CBT process simpler, more patient-friendly, paperless and modern. The app consists of basic CBT elements such as basic cognitive model, jotting down automatic thoughts, planning behavioural experiments, compiling coping cards, and most importantly, it helps to easily construct your own tables for therapy or to make notes in cooperation with your CBT therapist. Description of the functions above:

- **Cognitive model:** at the beginning of the CBT process, the basic cognitive model is explained. According to this, thoughts, feelings and behaviour are all connected, and individuals can move towards overcoming difficulties and meeting their goals by identifying and changing unhelpful or inaccurate thinking, problematic behaviour, and distressing emotional responses. The purpose of this function is to have the cognitive model as a reminder for the app users.

- **Start your thought diary:** this diary is a commonly used tool in CBT for monitoring thoughts, feelings and behaviours, as well as noticing problematic situations. The function has three levels: noticing the mentioned elements, answering or finding the alternative ways of thinking, and re-evaluating thoughts, feelings and behaviours. The therapist chooses the required levels and the number of sessions that are necessary for the patient. The patient can choose individually whether to continue using the function after the task has been completed.

- **Make your own table:** as the app is not diagnosis specific, there are numerous tables / worksheets in CBT that can help the patient to notice and change dysfunctional thoughts and/or behaviours. The therapist decides what task to fill in, and the app creates the corresponding worksheet(s). This is one function that separates the app from any other existing cCBT solutions, as it flexibly gives the therapist an opportunity to choose the ways that patient jots down homework.
• My coping cards: during the therapy procedure, patients learn to change unhelpful thoughts for more balanced thinking; however, people still tend to forget the strong and useful arguments and new core beliefs when they are in difficult situations. This is when they can use coping cards that are prepared in therapy or on their own.

• Behavioural experiment: this function in the CBT Basic app gives structure to behavioural experiments which are planned activities, based on experimentation or observation, undertaken by clients in sessions or in between sessions. The premade form in the app helps to test existing beliefs and/or help to test more adaptive beliefs by jotting them down and making conclusions. The therapist guides the patient how, why and when to fill in the forms.

Section 5 of the Generic Protocol (D3.1) provides more information on the included cCBT interventions and ccVC services.

4.5 Demographic characteristics of patients receiving cCBT through MasterMind

Overall, 365 patients have been included in the data analysis in this second wave. However, this number will increase in the final report, as most of the partners have improved their recruitment status since the data analysis was carried out.

Among all trial sites, the mean age of patients is 40,4 years (SD = 11,05). 34,7% of participants are male, and 65,3% are female.

With regard to the education, 38,4% of the participants received a secondary education, and 51,7% received a higher education. A total of 27 (7,2%) participants are immigrants. 204 (54,4%) of participants are currently employed. Data on residency will be provided in the final report.

Data on service referrals shows that the majority of patients have been referred to the cCBT service by GPs (33,3%) and other mental health professionals (36,8%), while 3,5% of participants have been referred by psychiatrists and 1,1% by psychologists.

Two main patterns have been detected. On the one hand, almost half of the patients were on medication for more than two months (42,7%) and on the other, 40,3% of the patients were not taking medication to treat depressive symptoms.

See Table 5 for more details of patient demographics.
### Table 5: Details of patient demographics

<table>
<thead>
<tr>
<th>Region</th>
<th>WALES</th>
<th>SP</th>
<th>IT</th>
<th>TR</th>
<th>EE</th>
<th>TOTAL</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>PHB-IRH</td>
<td>SALUD</td>
<td>Osakidetza</td>
<td>BSA</td>
<td>SERGAS</td>
<td>ASLTO3</td>
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<tr>
<td>Sample: n</td>
<td>161</td>
<td>10</td>
<td>10</td>
<td>41</td>
<td>-</td>
<td>75</td>
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<tr>
<td>Age years: mean (SD)</td>
<td>39,3 (13.03)</td>
<td>48,7 (16.34)</td>
<td>41 (9.98)</td>
<td>44,7 (13.72)</td>
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<td>51,7 (12.56)</td>
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<td>Gender: n (%)</td>
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<td>23</td>
<td>-</td>
<td>54</td>
</tr>
<tr>
<td>Education: n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>2</td>
<td>5</td>
<td>1</td>
<td>2</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>Secondary</td>
<td>78</td>
<td>2</td>
<td>0</td>
<td>16</td>
<td>-</td>
<td>28</td>
</tr>
<tr>
<td>Higher / University</td>
<td>79</td>
<td>2</td>
<td>8</td>
<td>18</td>
<td>-</td>
<td>44</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>Immigrated: n (%)</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>-</td>
<td>20</td>
</tr>
<tr>
<td>Employment status: n (%)</td>
<td>83</td>
<td>6</td>
<td>5</td>
<td>22</td>
<td>-</td>
<td>48</td>
</tr>
</tbody>
</table>
## D6.3 Intermediate Trial Report 2nd Wave (cCBT)

### Service referral: $n$ (%)

<table>
<thead>
<tr>
<th></th>
<th>WALES</th>
<th>SP</th>
<th>IT</th>
<th>TR</th>
<th>EE</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PHB-IRH</td>
<td>SALUD</td>
<td>Osakidetza</td>
<td>BSA</td>
<td>SERGAS</td>
<td>ASLTO3</td>
</tr>
<tr>
<td>General practitioner</td>
<td>0</td>
<td>5</td>
<td>9</td>
<td>33</td>
<td></td>
<td>73</td>
</tr>
<tr>
<td>Psychiatrist</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>6</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Psychologist</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>Other mental health professional</td>
<td>136</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>0</td>
</tr>
<tr>
<td>Self-referral</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>1</td>
</tr>
</tbody>
</table>

### Anti-depressant medication use: $n$ (%)

<table>
<thead>
<tr>
<th></th>
<th>WALES</th>
<th>SP</th>
<th>IT</th>
<th>TR</th>
<th>EE</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PHB-IRH</td>
<td>SALUD</td>
<td>Osakidetza</td>
<td>BSA</td>
<td>SERGAS</td>
<td>ASLTO3</td>
</tr>
<tr>
<td>Yes, for less than one month</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>-</td>
<td>4</td>
</tr>
<tr>
<td>Yes, for less than 2 months</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>9</td>
<td>-</td>
<td>5</td>
</tr>
<tr>
<td>Yes, for more than 2 months</td>
<td>78</td>
<td>8</td>
<td>1</td>
<td>16</td>
<td>-</td>
<td>37</td>
</tr>
<tr>
<td>No</td>
<td>69</td>
<td>1</td>
<td>7</td>
<td>16</td>
<td>-</td>
<td>29</td>
</tr>
</tbody>
</table>
4.6 Demographic characteristics of healthcare professionals involved in MasterMind

A total of 164 healthcare professionals have been included in the data analysis. 109 (66%) of the healthcare professionals involved are female, and 55 (34%) are male. 99 (60,4%) of the healthcare professionals in MasterMind are GPs, followed by other professionals (15,2%) or licensed psychologists (10%).

Among most of the healthcare professionals that are involved in the study, 111 (76,7%) have received training in cCBT and had field experience for 10 years or more (56,1%).

Less expertise has been observed in terms of experience with providing cCBT. Only 20,1% of the professionals have reported to have worked with cCBT more than 20 times, whereas a 49,4% of the specialists have worked between 0 and 4 times with cCBT.

See Table 6 for more details of healthcare professionals involved in Mastermind.
Table 6: Demographic characteristics of healthcare professionals

<table>
<thead>
<tr>
<th>Region</th>
<th>TOTAL</th>
<th>WALES</th>
<th>SP</th>
<th>IT</th>
<th>TR</th>
<th>EE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>PHB-IRH</td>
<td>SALUD</td>
<td>Osakidetza</td>
<td>BSA</td>
<td>SERGAS</td>
</tr>
<tr>
<td>Sample: n</td>
<td>164</td>
<td>21</td>
<td>3</td>
<td>48</td>
<td>38</td>
<td>-</td>
</tr>
<tr>
<td>Gender: n (%)</td>
<td></td>
<td>55</td>
<td>34%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td>6</td>
<td>1</td>
<td>14</td>
<td>18</td>
<td>-</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td>15</td>
<td>2</td>
<td>34</td>
<td>20</td>
<td>-</td>
</tr>
<tr>
<td>Profession: n (%)</td>
<td></td>
<td>99</td>
<td>60,4%</td>
<td>17</td>
<td>10%</td>
<td>0</td>
</tr>
<tr>
<td>General practitioner</td>
<td></td>
<td>0</td>
<td>1</td>
<td>37</td>
<td>32</td>
<td>-</td>
</tr>
<tr>
<td>Licensed psychologist</td>
<td></td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>Psychiatrist (in training)</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Psychologist (basic training)</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Licensed psychiatrist</td>
<td></td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Psychiatrist (in CBT training)</td>
<td></td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Psychiatrist (diploma in CBT)</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Psychiatrist (master)</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Psychiatrist (doctorate)</td>
<td></td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>-</td>
</tr>
</tbody>
</table>
# D6.3 Intermediate Trial Report 2nd Wave (cCBT)

## Region

<table>
<thead>
<tr>
<th>Region</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## WALES

<table>
<thead>
<tr>
<th>PHB-IRH</th>
<th>SALUD</th>
<th>Osakidetza</th>
<th>BSA</th>
<th>SERGAS</th>
<th>ASLTO3</th>
<th>ULSS9</th>
<th>METU</th>
<th>TUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>MH / community worker</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Central administrator</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>19</td>
<td>0</td>
<td>5</td>
<td>0</td>
<td>-</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Training in cCBT: n (%)</td>
<td>-</td>
<td>3</td>
<td>40</td>
<td>36</td>
<td>-</td>
<td>17</td>
<td>10</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Field experience: mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 3 years</td>
</tr>
<tr>
<td>3 years or more but less than 5 years</td>
</tr>
<tr>
<td>5 years or more but less than 10 years</td>
</tr>
<tr>
<td>10 years or more</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Experience with providing cCBT: mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-4 times</td>
</tr>
<tr>
<td>5-9 times</td>
</tr>
<tr>
<td>10-15 times</td>
</tr>
<tr>
<td>15-19 times</td>
</tr>
<tr>
<td>More than 20 times</td>
</tr>
</tbody>
</table>
4.7 Demographic characteristics of mental healthcare organisations involved in MasterMind

Table 7: Demographic characteristics of mental healthcare organisations

<table>
<thead>
<tr>
<th>Region</th>
<th>WALES</th>
<th>SP</th>
<th>IT</th>
<th>TR</th>
<th>EE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample: n</td>
<td>PHB-IRH</td>
<td>SALUD</td>
<td>Osakidetza</td>
<td>BSA</td>
<td>SERGAS</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Age (year of establishment): mean (range)</td>
<td>7 years (in existing establishment)</td>
<td>2011 (transference of competences from National Health to Regions)</td>
<td>1978</td>
<td>1935</td>
<td>1989</td>
</tr>
<tr>
<td>Number of units / departments: mean (range)</td>
<td>10</td>
<td>15 PC teams and 31 specialties in SC (BHCA)</td>
<td>19</td>
<td>25</td>
<td>7</td>
</tr>
<tr>
<td>Number of FTE employed: mean (range)</td>
<td>935 (BHCA)</td>
<td>30,000</td>
<td>1,200</td>
<td>Total FTE: 5,9 Mean:0,04 Range (0,006-1)</td>
<td>181</td>
</tr>
<tr>
<td>Turnover: mean (range)</td>
<td>£240,000.00</td>
<td>Annual Budget around 100M€ BHCA</td>
<td>69 M €</td>
<td>0</td>
<td>3%</td>
</tr>
<tr>
<td>Setting operated in: primary/basic or secondary/specialised</td>
<td>Primary and secondary care.</td>
<td>Primary and Secondary, Mental Health and Social-Health area</td>
<td>Primary and secondary care</td>
<td>Primary + Secondary</td>
<td>Secondary / specialised</td>
</tr>
</tbody>
</table>
4.8 Summary and discussion

After 25 months of the project, a total of 397 (17.26%) patients have been recruited for the cCBT part of the MasterMind project, together with 164 professionals and 25 healthcare organisations.

However this report only presents the results obtained after the data analysis in month 24. Thus, 365 patients have analysed after data analysis (Wales: n=161, SALUD: n=10, Osakidetza: n = 10, BSA: n=41, Piemonte: n= 75, Treviso: n=54, Turkey: n=7 and Estonia: n=7), and 164 professionals (Wales: n=21, SALUD: n=3, Osakidetza: n=48, BSA: n=38, Piemonte: N= 20, Treviso: N=13, Turkey: n= 3 and Estonia: n=18).

With regard to the demographic characteristics of the patients, the majority of the cases referred are female (65.3%); the mean age is 40.4 years (SD = 11.05).

The majority of patients have received a higher level of education (51.7%), and are employed (54.4%). Large proportions of patients have been referred to cCBT by a GP, and are not taking any antidepressant medication; hence cCBT is for most participants the only treatment for depression they receive.

Regarding the demographic characteristics of the professionals, the 164 specialists that are involved in the study are predominantly women (66%) and GPs (60.4%) who have received cCBT training (76.7%).

The large majority of participating healthcare professionals (56.1%) have field experience for 10 years or more. However, in terms of experience with providing cCBT, less expertise have been observed , as 49.4% of the participants have worked with cCBT between 0 and 4 times.
5. **Domain 2 and 3: Safety and clinical effectiveness**

5.1 **Introduction: what information is analysed in Domain 2 and 3**

The analysis within the context of domains 2 and 3 will establish the clinical effectiveness of the services in real world settings. The analysis for safety will focus on suicidality, drop-outs, and treatment attrition, together with safety issues as perceived by the healthcare professionals. In terms of clinical effectiveness, the variables included address the symptoms and methods for establishing symptoms, referral modalities, quality of life, access to the systems, and reasons for drop-outs and attrition rates.

Data for these domains will be quantitative, and will be used to answer these project objectives: objective #1: To identify barriers and facilitators that influences the implementation of cCBT and ccVC for treating depression in routine practice; objective #2: To assess clinical change of patients’ depressive symptoms when treated with cCBT and ccVC in routine practice; objective #4: To assess patients’ safety in terms of their health when provided with cCBT and ccVC in routine practice; and objective #7: To assess the transferability of implementation and up scaling of cCBT and ccVC in routine practice in different care contexts. The instruments used to collect the data include Routine Outcome Measurements (ROM), the treatment platforms, and online questionnaires.

Together with domains 1 and 4, these results will enable drawing conclusions in terms of the acceptability and appropriateness of the services in alleviating depressive symptoms. Acceptability is the perception among patients that the received treatment is agreeable, palatable, or satisfactory\(^{29}\). Appropriateness is the perceived fit, relevance, or compatibility of the treatment for the patient in addressing his or her mental disorder\(^{30}\). Acceptability and appropriateness will be measured through:

a) establishing changes in depressive symptoms and quality of life (domain 3);

b) establishing perceived satisfaction with the treatment (domain 4);

c) establishing the perceived usability of the treatment (domain 4); and

d) treatment attrition (domain 2 and 3).

The methods for measuring the symptoms of depression adhere to routine practice, and will be registered in terms of: clinical interview; professional clinical judgement; or a symptom questionnaire. Symptoms are recorded in terms of no, mild, moderate or severe symptoms according to routine practice diagnostic procedures (e.g. PHQ-9, BDI, etc.) using appropriate transformation scales if needed.

5.2 **Clinical safety in MasterMind**

This section briefly describes clinical safety, which serves as a valuable adjunct to risk assessment for those who have had a suicide attempt, or a suicide ideation.

---

\(^{29}\) Proctor E. et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Springer US, 2011

Three suicide ideations have been detected in Treviso, and in Aragón one alarm was automatically generated by the tool because one patient selected the PHQ-9 item related to self-damage. After this alarm, the patient was contacted (no previous suicide ideation had been detected before) and a new treatment was started for this person. It was considered as a drop out, but this person can still access the programme. This is considered important for the professionals, because they think that this situation could have been difficult to detect under normal treatment (face-to-face visits).

In the rest of the trial sites, no suicide ideations or attempts have been registered.

5.3 Clinical effectiveness in MasterMind

With the aim of analysing the clinical effectiveness of clinical symptoms, data for a total of 29 patients have been registered at both baseline and the end of the treatment period. Due to the low number of results obtained after the data analysis, it is difficult to come up with a proper comparative analysis of the clinical symptoms. Four trial sites (PHB-IRH, ASLTO3, ULSS9 and TUT) have already reported data.

Among these sites, the moderate symptom has been the most frequent clinical symptom recorded (79.3%) during the baseline period.

When the clinical symptoms at the end of the treatment have been analysed, in general, it has led to an equal level of clinical symptoms between moderate (44.8%) and mild symptoms (41.4%). That means that from the baseline period to the end of the treatment, the moderate symptom has decreased by 56.5%.

At the moment no severe or very severe symptoms have been recorded.

See Table 8 for more details of clinical effectiveness in Mastermind.

Table 8: Clinical symptoms

<table>
<thead>
<tr>
<th>Period</th>
<th>WALES</th>
<th>IT</th>
<th>EE</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PHB-IRH</td>
<td>ASLTO3</td>
<td>ULSS9</td>
<td>TUT</td>
</tr>
<tr>
<td>Clinical symptoms: n (%)</td>
<td>23</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>No symptoms are experienced</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Symptoms are mild</td>
<td>5</td>
<td>10</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Symptoms are moderate</td>
<td>18</td>
<td>11</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Symptoms are severe</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Symptoms are very severe</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

B: Baseline; E: End of the treatment
Table 9 shows the clinical frequency of depressive episodes. A total of 351 patients have been registered during baseline period. 18.5% of the population have suffered from episodes between 1 and 3 years, and 16.8% from episodes for more than 10 years.

Table 9: Description of the depressive episodes

<table>
<thead>
<tr>
<th>Region</th>
<th>Total</th>
<th>Wales</th>
<th>PHB-IRH</th>
<th>SALUD</th>
<th>Osakidetza</th>
<th>SP</th>
<th>BS</th>
<th>SERGAS</th>
<th>IT</th>
<th>TR</th>
<th>EE</th>
<th>METU</th>
<th>TUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 4 weeks</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Between 4 and 8 weeks</td>
<td>24</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>4</td>
<td>-</td>
<td>11</td>
<td>7</td>
<td>7</td>
<td>0</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Between 8 and 12 weeks</td>
<td>30</td>
<td>6</td>
<td>0</td>
<td>1</td>
<td>7</td>
<td>-</td>
<td>15</td>
<td>0</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Between 3 and 6 months</td>
<td>53</td>
<td>13</td>
<td>2</td>
<td>3</td>
<td>10</td>
<td></td>
<td>17</td>
<td>7</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Between 6 and 1 year</td>
<td>46</td>
<td>21</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>-</td>
<td>8</td>
<td>8</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Between 1 and 3 years</td>
<td>65</td>
<td>30</td>
<td>1</td>
<td>2</td>
<td>9</td>
<td></td>
<td>8</td>
<td>13</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>3 to 5 years</td>
<td>28</td>
<td>18</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>-</td>
<td>4</td>
<td>5</td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>5 to 10 years</td>
<td>40</td>
<td>26</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>-</td>
<td>4</td>
<td>8</td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>More than 10 years</td>
<td>59</td>
<td>46</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>-</td>
<td>3</td>
<td>6</td>
<td></td>
<td>0</td>
<td></td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

5.4 Quality of life in MasterMind

This section analyses the quality of life, regarding satisfaction with life and mental health. A total of 46 patients have been registered between the baseline period and end of the treatment in three trial sites: PHB, ASLTO3 and TUT.

With regards to satisfaction with life, 46.3% of patients have felt mixed feelings. 34.8% perceive their life as mostly satisfied, whereas 28.3% of patients described themselves as mostly dissatisfied.

In relation to their satisfaction with mental health, 27.6% of patients have mixed feelings, while 39.6% are displeased or mostly dissatisfied.

See Table 10 for more details of quality of life in Mastermind.
Table 10: Satisfaction with life and satisfaction with mental health

<table>
<thead>
<tr>
<th>Region</th>
<th>WALES</th>
<th>IT</th>
<th>EE</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>E</td>
<td>B</td>
<td>E</td>
</tr>
<tr>
<td>Satisfaction with life: n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Couldn't be worse</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Displeased</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Mostly dissatisfied</td>
<td>6</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Mixed</td>
<td>7</td>
<td>9</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Mostly satisfied</td>
<td>7</td>
<td>7</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Pleased</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Couldn't be better</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Satisfaction with mental health: n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Couldn't be worse</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Displeased</td>
<td>9</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Mostly dissatisfied</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Mixed</td>
<td>5</td>
<td>9</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Mostly satisfied</td>
<td>2</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pleased</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Couldn't be better</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

B: Baseline; E: End of the treatment

5.5 Analyses of patients who stopped the treatment (dropouts)

Currently there is no data on dropouts.

5.6 Discussion of findings

Overall, the majority of the patients showed moderate symptoms during the baseline period. However, at the end of the treatment, the most common clinical symptoms among the patients were the moderate and mild symptoms. Note that at the moment no severe or very severe symptoms have been recorded.
Among the low data recorded, three suicide ideations were reported in Treviso, and one alarm has been detected in Aragón when one patient selected the PHQ-9 item related to self-damage.

More patients report mixed feelings about their satisfaction with life, and having mixed feelings or being displeased with their mental health at intake to treatment.

At this stage of the project, there is no information in relation to the dropout reasons.
6. **Domain 4: Patient and healthcare professional perspectives**

6.1 **Introduction – what information is analysed in Domain 4**

Domain 4 addresses the perceived satisfaction of both patients and healthcare professionals, and the usability of the programmes. The perspectives will be measured through validated self-reported measures (CSQ-8/3 and SUS), and provide an indication of the acceptance and appropriateness of the services in addressing the depressive disorder. The data on satisfaction includes variables on quality, type, needs, complexity and overall satisfaction. Data on usability will describe usage, complexity, consistency, confidence, and level of integration.

Domain 4 aims to answer research objectives: objective #1: To identify barriers and facilitators that influence the implementation of cCBT and ccVC for treating depression in routine practice; objective #5: To assess the perceived satisfaction and perceived usability of cCBT and ccVC; and objective #7: To assess the transferability of implementation and up scaling of cCBT and ccVC into routine practice in different care contexts.

Together with domains 1, 2, 3, and 5, these results will enable to draw conclusions in terms of the acceptability and appropriateness of the services in alleviating depressive symptoms. The results will be triangulated (mixed-methods) with the focus group discussions with the healthcare professionals (domain 4) and organisations (domain 5). This triangulation will provide an understanding of the meaning (qualitative) of the facts (quantitative) for the healthcare professionals and organisations, and the interplay of both stakeholders.

More specifically, data will provide information on patients' perspectives towards the services implemented within the MasterMind project, and the healthcare professional perspective towards these services, by analysing and interpreting data retrieved from focus group interviews and structured interviews.
7. **Domain 5: Economic aspects**

7.1 **Introduction: what information is analysed in Domain 5**

Domain 5 provides insights into the costs associated with the implementation of the services. Both direct and indirect costs related to the investment to implement the services are collected, as well as estimates of the recurring costs to maintain and operate the services. The quantitative data will be enriched with qualitative data about the envisioned funding strategies and business cases by the healthcare organisations, as well as a view on the barriers and facilitators that organisations perceive in implementing and maintaining the services in routine practice.

Data analysed in domain 5 attempts to answer research objectives: objective #1: To identify barriers and facilitators that influences the implementation of cCBT and ccVC for treating depression in routine practice; objective #3: To assess the costs associated with implementing and large-scale uptake of cCBT and ccVC for treating depression in routine practice; and objective #7: To assess the transferability of implementation and up scaling of cCBT and ccVC into routine practice in different care contexts.

The results will enable drawing conclusions in terms of implementation costs.

Data for the economic evaluation will be collected as part of the qualitative data collection process that will take place in the next year.

Within the final trial report, data will be provided on investment (incidental effort needed to implement cCBT service and investment costs to provide the infrastructure), as well as additional time per person spent on initial training and supervision. Mean direct and indirect cost per cCBT session will be provided per trial site.
7.2 Investments

Table 11: Summary of Investments for the implementation of the cCBT service

<table>
<thead>
<tr>
<th>Region</th>
<th>Wales</th>
<th>SP</th>
<th>IT</th>
<th>TR</th>
<th>EE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHB-IRH</td>
<td>SALUD</td>
<td>Osakidetza</td>
<td>BSA</td>
<td>SERGAS</td>
<td>ASLTO3</td>
</tr>
<tr>
<td>Incidental efforts (time in FTE) needed of support staff to implement cCBT: mean (SD)</td>
<td>2.5 FTE</td>
<td>0.5 FTE (6mm approx)</td>
<td>0.5 FTE</td>
<td>NA</td>
<td>0.6 FTE (6mm approx)</td>
</tr>
<tr>
<td>Investment costs for additional materials such as ICT infrastructure: mean (SD)</td>
<td>£58,896</td>
<td>3500€</td>
<td>14.870€</td>
<td>60.000€</td>
<td>506 €</td>
</tr>
<tr>
<td>Extra time per person for initial training and supervision: (y/n) %</td>
<td>7.5 hours per person</td>
<td>4 hours per professional</td>
<td>7 hours per professional</td>
<td>70 hours per professional</td>
<td>8 hours per professional</td>
</tr>
</tbody>
</table>

ASLTO3

1) Estimated time: 24 hours per month. This estimated effort represents about 18% of time in FTEs.

2) Estimated investments costs: about 40,207 €. This estimated amount includes costs related to the use and maintenance of the cCBT tool provided by an external ICT provider and other costs related to materials and technical services of the MasterMind local team to support the health professionals / patients in using the cCBT tool. This estimated amount includes costs encountered until now, and calculated as the investment of our unit without including the EC contribution.

3) Estimated time: 28 hours per month. This estimated effort represents about 22% of time in FTEs.

ULSS9

1. Data entered in the above table should be considered partial.

2. At this stage, the incremental effort needed to implement cCBT has a particular feature. There were 34 FTE for informal support to realise the iFightDepression (iFD) Italian version (the online tool and website for the provision of CBT). We have to consider that the support for the Italian version of the platform is a type of activity more linked to the development of the platform than the specific implementation of the cCBT programme.
For that reason, we have to evaluate with the other partners how to evaluate and taking into account this specific investment cost.

3. Investment levels in ICT infrastructures are minimal. Our best estimate is: one-hour work of technical staff (one person) to install two workstations and the related investment costs to buy the materials (laptops). Moreover, the laptops bought are not only used for the MasterMind project purposes, but also for all current activities of the medical centres involved.

### 7.3 Recurrent operational costs

Table 12: Summary of cost for the maintenance of the cCBT service

<table>
<thead>
<tr>
<th>WALES</th>
<th>SP</th>
<th>IT</th>
<th>TR</th>
<th>EE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHB-IRH</td>
<td>SALUD</td>
<td>Osakidetz a</td>
<td>BSA</td>
<td>SERGA</td>
</tr>
<tr>
<td>Direct costs of cCBT for one session: mean (SD)</td>
<td>£35.32 per patient, per session. (there are 8 sessions in total)</td>
<td>14,6 €</td>
<td>95 €</td>
<td>NA</td>
</tr>
<tr>
<td>Indirect costs spent on overheads of cCBT for one session: mean (SD)</td>
<td>£10.60 per patient, per session. (there are 8 sessions in total)</td>
<td>28,5 €</td>
<td>NA</td>
<td>39,72 €&lt;br&gt; Around 33€ for one session</td>
</tr>
</tbody>
</table>

### 7.4 Sustainability of services in routine practice

Table 13: Description of the predicted sustainability of the cCBT service

<table>
<thead>
<tr>
<th>WALES</th>
<th>SP</th>
<th>IT</th>
<th>TR</th>
<th>EE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHB-IRH</td>
<td>SALUD</td>
<td>Osakidetz a</td>
<td>BSA</td>
<td>SERGA</td>
</tr>
<tr>
<td>Service reimbursed and by whom (health insurance, state etc.)</td>
<td>State</td>
<td>No, it is assumed by the same organisation</td>
<td>No reimbursed</td>
<td>No reimbursed</td>
</tr>
<tr>
<td>If reimbursed, is this a success of Mastermind?</td>
<td>N.A</td>
<td>NA</td>
<td>N.A</td>
<td>N.A</td>
</tr>
<tr>
<td>Reimbursement per session [€], total service per patient [€]</td>
<td>N.A</td>
<td>NA</td>
<td>N.A</td>
<td>N.A</td>
</tr>
<tr>
<td>Some explanations about the comparability to reimbursement of Face-to-Face Therapy</td>
<td>N.A</td>
<td>NA</td>
<td>N.A</td>
<td>N.A</td>
</tr>
</tbody>
</table>
7.5 Discussion of findings

The cost effectiveness analysis will provide an estimate of the cost of changing severity levels for the patients in a region and at consortium level. The project will carry out a cost effectiveness analysis based on the total cost (cost of implementing + running cost) for the services, and revenues (savings, payments, and external budgets) relative to the effects of the service. For this analysis, changes in symptoms have been selected as the primary effect of the services. The initial findings provided above will be updated and completed in the final evaluation report. Because of the inconsistency and incompleteness of data at this stage of the project, no cost effectiveness analysis has been conducted.
8. Domain 6: Organisational aspects

8.1 Introduction: what information is analysed in Domain 6

As per D3.1 Scientific study protocol, domain 6 aims to provide insights into organisational aspects and perspectives in implementing and up-scaling the cCBT and ccVC services in routine practice. Variables include quantitative information on the organisation profile (as part of domain 1) and estimates of case load, and qualitative information retrieved via focus group discussions and semi-structured interviews on issues of leadership engagement (in terms of commitment and implementation strategies), resources (time and savings), perceived factors for implementation success, and innovation climate (including information on knowledge and beliefs about the services, self-efficacy in using the services, individual state of change, identification with the organisation, support and awards, and relative priority). Findings will be triangulated between both quantitative data and qualitative data, and between healthcare professionals and organisational perspectives (organisations).

The analyses performed at the end of the study period will enable drawing answers to the research questions: objective #1: To identify barriers and facilitators that influence the implementation of cCBT and ccVC to treat depression in routine practice; objective #3: To assess the costs associated with implementing and large-scale uptake of cCBT and ccVC to treat depression in routine practice; objective #5: To assess the perceived satisfaction and perceived usability of cCBT and ccVC; and objective #7: To assess the transferability of implementation and up-scaling of cCBT and ccVC in routine practice in different care contexts.

Findings from domain 6, together with domains 1-5 and 7, will provide insights into the acceptability and appropriateness from the perspective of healthcare professionals, and the sustainability of the services in routine practice as seen from the viewpoint of the organisations.

This section will be completed in the Final Trial Evaluation report.

8.2 Case-load of healthcare professional

[Qualitative discussion of:
• Caseload
• Working arrangement
• Case management]

8.3 Leadership engagement

[Qualitative discussion of:
• Commitment – org. view
• Commitment – healthcare professional view]
8.4 Resources

[Qualitative discussion of:
- Time – org. view
- Time – healthcare professional view
- Therapist time
- Resource savings]

8.5 Perspectives on implementation

[Qualitative discussion of:
- Factors for success – org view
- Factors for success – healthcare professional view]

8.6 Innovation culture

[Qualitative discussion of:
- Knowledge and beliefs about the intervention
- Self-efficacy
- Individual stage of change
- Healthcare professional identification with organisation (commitment and loyalty)
- Support
- Rewards (recognition and appreciation)
- Relative priority]

8.7 Discussion of findings

Any initial finding, to be updated / completed in the final evaluation report
9. Domain 7: Socio-cultural, ethical and legal aspects

9.1 Introduction: what information is analysed in Domain 7

Domain 7 is concerned with the broader context of the implementation. In MasterMind, it is concerned with two issues: public policy and regulations, and liability. Variables include information on clinical guidelines and perspectives of healthcare professionals and organisations towards the value and use of clinical guidelines in everyday practice. Additionally, the analysis for domain 7 also engages in establishing the competitive value of implementing innovations such as the cCBT and ccVC services, where applicable. Liability analysis will address the issue of clinical and legal liability of healthcare professionals and organisations in employing (partly) automated ICT systems in delivering care to patients. Data will be retrieved through the focus group discussions with healthcare professionals and semi-structured interviews with representatives of the service providers. Please refer to D3.1 Scientific study protocol (version 2) for more information on the details of the design and data collection for this domain.

Data analysis for domain 7 will enable answering the following research objectives: objective #1: To identify barriers and facilitators that influences the implementation of cCBT and ccVC for treating depression in routine practice; objective #5: To assess the perceived satisfaction and perceived usability of cCBT and ccVC; and objective #7: To assess the transferability of implementation and up scaling of cCBT and ccVC into routine practice in different care contexts.

Findings from domain 7, together with domains 1-6, will provide insights into the acceptability and appropriateness of the services from the perspective of healthcare professionals, and the sustainability of the services in routine practice as seen from the viewpoint of the organisations.

More specifically, data will give information on the public policy and regulations at the different trial sites (clinical guidelines in practice, and public image through benchmarking) and potential conflicts within a qualitative discussion of professional liability.

This section will be completed in the Final Trial Evaluation report.

9.2 Public policy and regulation
[Qualitative discussion of:
- Clinical guidelines in practice and
- Public image through benchmarking]

9.3 Conflict
[Qualitative discussion of professional liability]
9.4 Discussion of findings

Any initial finding, to be updated/completed in the final evaluation report
10. Transferability assessment

This section will assess the transferability of results, i.e. determining whether particular demographic, clinical, organisational or economical issues have affected the outcome, and to what extent the results can be transferred to e.g. a larger patient group or other organisations. The section will be based on the MAST model, and will assess scalability and generalisability of the domains in the MAST model.

This section will be completed in the Final Trial Evaluation report.
11. Conclusions

During the first months of implementation, from month 19 to month 25, 397 patients have been recruited by the second wave pilot sites. The trials started more slowly than expected with regard to patients and professionals inclusion.

Based on second wave pilot experience, some barriers have been identified that seem to be some of the reasons for these delays; these include organisational constraints (lack of time, lack of resources for effective implementation, etc.), the necessity to integrate their cCBT programme in their organisation’s ICT corporate systems (e.g. Basque Country and Galicia), the high number of patient dropouts (e.g. Wales and Estonia), and the collaboration problems of the health professionals involved in the study (e.g. Piemonte, Wales and Estonia).

With the aim of increasing recruitment numbers and to solve these problems, several new strategies have been adopted by the sites. Some of the solutions adopted were related to the inclusion of more professionals in the study (e.g. Aragon, Sargas, Basque Country, Badalona, Estonia and Piemonte), with the development of more dissemination activities (e.g. Badalona, Estonia, Piemonte and Basque Country), or providing more training material, training sessions, and intermediate sessions to the professionals (SALUD, Basque Country, Badalona, and Estonia).

According to the information recovered by each trial site of the second wave, around 300,000 patients could be reached with the local cCBT programmes at this stage of the project. The number of eligible patients was estimated from the prevalence of depression and the inclusion or exclusion criteria defined by each pilot site.

Regarding the demographic characteristic among the patients included in the study, at seven of the eight study sites, the prevalence of depressive disorder was higher among the female population than among males. Data on service referral showed that the majority of patients have been referred to the cCBT service by GPs and other mental health professionals.

A variety of social factors have been considered in this study. Some of the outcomes showed that the prevalence of depressive disorder was higher among patients that have received higher education and are currently employed.

In relation to the consumption of antidepressant, at five of the eight study sites, the patients were on medication to treat depressive symptoms for more than two months.

Concerning the demographic characteristic of the professionals engaged in the study, in most of the sites, the healthcare professionals were mainly women.

Overall, the majority of the specialists involved were GPs that have received training in cCBT and had field experience for 10 years or more. However in terms of experience with providing cCBT, there is less expertise: most of the specialists have worked only between 0 and 4 times with cCBT.

This study found that patients have not attempted suicide. However, three suicide ideations have been detected, and one alarm was automatically generated by the tool because one patient selected the PHQ-9 item related to self-damage.
Regarding clinical effectiveness, the preliminary data analysis showed that the most common depressive disorder during the baseline period among patients was a moderate depression. However, when the clinical symptoms were analysed at the end of the treatment, then the level of depression has led to an equal level of clinical symptoms between moderate and mild symptoms.

Participants identified as having depressive episodes at baseline between 3 and 6 months and episodes for more than 10 years.

With regard to the quality of life, in terms of the satisfaction with life, overall, patients have perceived their life as mostly satisfied or with felt mixed feelings. Whereas, regarding the satisfaction with mental life, patients have alleged mixed feelings and had displeased satisfaction.

The final report will provide further information and insights on a number of topics, including: organisational aspects; socio-cultural, ethical and legal perspectives; the patients' and healthcare professionals' perspectives on the cCBT solutions; and economic aspects of the trial. The qualitative part of the study conducted at the end of the trial will add additional depth and understanding to the results. Finally, a specific section will give information on the important topic of transferability of results to other patient groups, organisation groups and regions.

In conclusion, the project already at mid-point is over-exceeding expectations with regard to multiple aspects of the project, such as recruitment numbers and the possibilities for comparison of results. Within the remainder of the project, the goals are to: a) further increase recruitment numbers, especially providing a greater amount of post-treatment data; b) include a higher number of participating organisations and regions; c) further sustain the knowledge exchange between wave one and wave two partners; and d) prepare the qualitative post assessment.
Appendix A: Study Objectives

The MasterMind Consortium intends to implement and up-scale evidence-based computerised Cognitive Behavioural Therapy (cCBT) services for depressed adults across a number of EU and Associated Countries, and from this implementation: a) identify barriers and success factors to implement cCBT on a large scale and b) to recommend successful strategies for implementing cCBT in different contexts. Additionally, MasterMind aims to implement video-conference-enabled collaborative care (ccVC) for patients who are treated for depression. Using the lessons learnt, the Consortium will develop guidelines and a tool kit for promoting and facilitating the broader implementation across Europe of a safe, effective and efficient service that is supported by relevant stakeholders.

For these purposes, the present study pursues the following seven objectives:

1. To identify the factors which promote or hinder the implementation of cCBT and ccVC for treating depression in routine practice.

2. To assess change of patients’ depressive symptoms when treated with cCBT and ccVC in routine practice.

3. To assess the costs associated with implementation and large-scale uptake of cCBT and ccVC for treating depression in routine practice.

4. To assess patients’ safety in terms of their mental health when provided with cCBT and ccVC in routine practice.

5. To assess the perceived satisfaction and perceived usability of cCBT and ccVC in: a) Patients when treated for depression; b) Healthcare professionals when treating patients suffering from depression; c) Healthcare professionals when using ccVC in a collaborative care setting.

6. To identify the reach of cCBT and ccVC in routine practice through assessing general patient characteristics.

7. To identify how to implement cCBT and ccVC at large scale in routine practice in different care contexts.