MENTUPP

Data management plan

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Full Name	Short Name	Beneficiary Number	Role
UNIVERSITY COLLEGE CORK – NATIONAL UNIVERSITY OF IRELAND, CORK	UCC	1	Coordinator
EUROPEAN ALLIANCE AGAINST DEPRESSION EV	EAAD	2	Beneficiary
KATHOLIEKE UNIVERSITEIT LEUVEN	KU Leuven	3	Beneficiary
DET NATIONALE FORSKNINGSCENTER FORARBEJDSMILJO	NRCWE	4	Beneficiary
TERVEYDEN JA HYVINVOINNIN LAITOS	THL	5	Beneficiary
THE UNIVERSITY OF STIRLING	NMAHP-RU	6	Beneficiary
SEMMELWEIS EGYETEM	SEM	7	Beneficiary
STICHTING KENNISCENTRUM PHRENOS	PHRENOS	8	Beneficiary
QENDRES SE SHENDETIT DHE MIREQENIES KOMUNITARE	CCHW	9	Beneficiary
ZYRA PER SHENDET MENDOR	ZSMKOS	10	Beneficiary
LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE ROYAL CHARTER	LHSTM	11	Beneficiary
CONSORCIO MAR PARC DE SALUT DE BARCELONA	IMIM	12	Beneficiary
NATIONAL SUICIDE RESEARCH FOUNDATION	NSRF	13	Beneficiary
INTERNATIONAL ASSOCIATION FOR SUICIDE PREVENTION	IASP	14	Beneficiary
PINTAIL LTD	PT	15	Beneficiary
GRIFFITH UNIVERSITY	AISRAP	16	Beneficiary
MATES IN CONSTRUCTION (AUST) LTD	MIC	17	Beneficiary

D8.1 Data Management Plan

Version History

Version number (date)	Details
1.0 (30.06.20)	Initial submission to EC
2.0 (19.03.21)	Changed MINDUP to MENTUPP throughout the deliverable

1 Executive Summary

The D8.1 deliverable includes the data management plan (DMP) of MENTUPP. It provides (1) a summary of the data that are collected within MENTUPP, (2) how the data are made FAIR (findable, accessible, interoperable and reusable), (3) where the data will be deposited, (4) how the data will be secured, and (5) how the data will be treated to conform data protection regulations and GDPR.

2 Introduction & Background

The DMP is developed for the European Commission as well as for the MENTUPP consortium partners and aims to inform everyone about:

- What types and formats of data will be generated and collected during MENTUPP
- How the data will be processed and handled by all consortium partners
- Whether the data will be shared or made open-access, and how this will occur
- How the data will be curated and preserved after the MENTUPP project

All consortium partners are expected to adhere to the conditions as prescribed in the DMP.

3 Approach

The DMP was developed collaboratively with UCC and in close liaison with the data protection officer and the research coordination office of KU Leuven. The document was reviewed by several MENTUPP team members and their comments were systematically incorporated.

Importantly, the DMP is a living document and will be updated two more times throughout the further course of the project to ensure that it encompasses any significant changes and new decisions regarding the management of the data:

- A second revision of the draft will follow in month 24
- A third revision will follow in month 46

4 Results

The output of this deliverable is the DMP which can be found in Appendix 1.

5 Impact & Conclusion

The DMP is a key document to ensure good data management and is the first output of Task 8.1 in WP8. It describes the data management life cycle for the data that will be collected, processed and/or generated by MENTUPP, and allows that the research data will be findable, accessible, interoperable and re-usable (FAIR) by providing information on:

- The handling of research data during and after the end of the project
- What data will be collected, processed, and/or generated
- Which method and standards will be applied
- Whether data will be shared/made open access and
- How data will be curated and preserved (including after the end of the project)

The DMP has an impact on all work packages that are involved in data collection, data processing and/or data generation (WP2 to 9, and WP11).

6 Appendices

Appendices to this deliverable

Appendix 1: MENTUPP Data Management Plan

Appendix 1

Project Number: 848137

Project Acronym: MENTUPP

Project title: Mental Health Promotion and Intervention in Occupational Settings

DATA MANAGEMENT PLAN

Version 1.0

Date: 30 June 2020

PROJECT DETAILS

Acronym: MENTUPP
Title: Mental Health Promotion and Intervention in Occupational Settings

Project coordinator: UCC (Ella Arensman)

Programme: Horizon 2020
Topic: Mental Health in the Workplace
Type: Research and Innovation Action (RIA)

Start: 1 January 2020
Duration: 48 months

Website: https://www.mentuppproject.eu/

List of Beneficiaries:

No.	Name organisation	Short name	Country
1	University College Cork – National University of Ireland, Cork	UCC	Ireland
2	European Alliance Against Depression ev	EAAD	Germany
3	Katholieke Universiteit Leuven	KU Leuven	Belgium
4	Det Nationale Forskningscenter for Arbejdsmiljø	NRCWE	Denmark
5	Terveyden ja Hyvinvoinnin Laitos	THL	Finland
6	The University of Stirling	NMAHP-RU	UK
7	Semmelweis Egyetem	SEM	Hungary
8	Stichting Kenniscentrum Phrenos	PHRENOS	Netherlands
9	Qendres se Shendetit dhe Mireqenies Komunitare	CCHW	Albania
10	Zyra per Shendet Mendor	ZSMKOS	Kosovo
11	London School of Hygiene and Tropical Medicine Royal Charter	LSHTM	UK
12	Consorcio Mar Parc de Salut de Barcelona	IMIM	Spain
13	National Suicide Research Foundation	NSRF	Ireland
14	International Association for Suicide Prevention	IASP	USA
15	Pintail Ltd	PT	Ireland
16	Griffith University	AISRAP	Australia
17	Mates in Construction (aust) ltd	MIC	Australia

1. Deliverable

Number:	D8.1
Work package:	Evaluation of the MENTUPP intervention pilot and cRCT (WP8)
Lead beneficiary:	KU Leuven
Dissemination level:	Public
Nature:	Open Research Data Pilot (ORDP)
Submission date:	30 June 2020
Authors:	Evelien Coppens (KU Leuven) Fotini Tsantila (KU Leuven) Chantal Van Audenhove (KU Leuven)
Other contributors:	All partners

2. Executive summary

Depression and anxiety are the most prevalent mental health difficulties in the workplace in the EU, causing immense suffering and costing the global economy €1 trillion each year in lost productivity. Certain sectors – in particular, the construction, the health, and the ICT sector – have an elevated risk of mental health difficulties, with those working in Small and Medium Enterprises (SMEs) being particularly vulnerable. However, most SMEs have limited capacity to address mental health promotion and provide mental health interventions to staff. As SMEs comprise more than 90% of all EU businesses, there is a huge potential to influence population health.

MENTUPP aims to improve mental health and wellbeing in the workplace by developing, implementing and evaluating a comprehensive, multilevel intervention targeting both clinical (depressive, anxiety disorders) and non-clinical (stress, burnout, wellbeing, depressive symptoms) mental health issues, as well as combating the stigma of mental (ill-) health. The intervention will be tailored for SMEs in construction, healthcare and ICT and assessed in a multi-country Cluster Randomised Controlled Trial. The primary aim is to improve mental health in the workplace, with a secondary aim to reduce depression and suicidal behaviour.

The two overall aims of MENTUPP will be achieved by the following six objectives:

1. To systematically review existing evidence-based interventions, targeting:
    - Stress, burnout, wellbeing, and depressive symptoms (non-clinical)
    - Depressive disorders and co-morbid anxiety according to ICD-10 (clinical)
    - De-stigmatisation of mental (ill-)health
2. To adapt and integrate these interventions to develop the multilevel MENTUPP intervention, tailored for workplace sector, gender and mode of delivery (face-to-face vs. online) and accounting for implementation factors, which will be delivered via the MENTUPP Hub online platform.
3. To conduct a pilot assessing the MENTUPP intervention in SMEs in construction, health, and ICT in at least two different countries, using implementation science analyses and to optimise the intervention post-pilot.
4. To conduct a multi-country cluster randomised controlled trial (cRCT) to assess the effectiveness of the optimised MENTUPP intervention by looking at: improvements in the mental health of

employees and employers, and cost-effectiveness and implementation factors in SMEs in the target sectors in all nine implementation countries.
5. To further optimise the MENTUPP intervention materials for wider replication post-cRCT.
6. To promote the MENTUPP project and intervention to stakeholders, including policy makers, insurers, social partners, regulatory authorities, and the general public at both European and global levels.

MENTUPP will be conducted by an interdisciplinary consortium by means of 11 work packages:

- WP1: MENTUPP Project management
- WP2: Developing interventions for wellbeing, stress, burnout, and depressive symptoms
- WP3: Development of interventions for depressive disorders and comorbid anxiety
- WP4: Develop MENTUPP interventions for stigma reduction
- WP5: Evidence-base for the implementation of the MENTUPP intervention programme
- WP6: Development and maintenance of the MENTUPP online platform: MENTUPP-hub
- WP7: Pilot implementation of the MENTUPP intervention
- WP8: Evaluation of the MENTUPP intervention pilot and cRCT
- WP9: Implementation of the optimised MENTUPP intervention - a cRCT
- WP10: Communication, dissemination, and exploitation
- WP11: Ethics requirements

Data will be reused, collected, or generated in WP2 to 10.

3. Purpose and scope of the data management plan (DMP)

The DMP is developed for the European Commission as well as for the MENTUPP consortium partners and aims to inform them about:

- What types and formats of data will be generated and collected during the MENTUPP project
- How the data will be processed and handled by all consortium partners
- Whether the data will be shared or made open-access, and how this will occur
- How the data will be curated and preserved after the MENTUPP project

The DMP is a living document. At this moment, some questions concerning the management of the data are still open for discussion and/or have only a provisional answer. The DMP will be updated two times throughout the further course of the project to ensure that it encompasses any significant changes and newly made decisions regarding the management of the data:

- A first draft of the DMP is made in month 6 of the project
- A first revision of the draft will follow in month 24
- A final revision will follow in month 46

All consortium partners are expected to adhere to the conditions as prescribed in the DMP. The measures that are taken in that regard are described in table 2 (accountability).

4. Data summary

4.1. Purpose of the data collection and its relation to the objectives of the project

Objective 1: to systematically review existing evidence-based interventions, targeting stress, burnout, wellbeing, depressive symptoms, depressive disorders and co-morbid anxiety, and de-stigmatisation of mental health

Within MENTUPP, six systematic reviews and one Delphi study will be carried out.

The six systematic reviews relate to:

- Existing interventions for wellbeing, stress, burnout, and depressive symptoms (three reviews, one for each of three sectors: construction, ICT, and health)
- Existing interventions for depressive disorders and comorbid anxiety
- Existing interventions for stigma reduction
- Barriers and facilitators of the implementation of mental health programs

The Delphi study will approach experts in the field about their experience with (1) interventions targeting stress, burnout, wellbeing, depressive symptoms, depressive disorders and co-morbid anxiety, and de-stigmatisation of mental health and (2) implementation of interventions.

Responsible work packages: WP2 to 5

Data collected:

- Systematic reviews of scientifically published and grey literature: reuse of published reports (WP2 to 5)
- Consultation of experts in nine countries: (Albania, Australia, Finland, Germany, Hungary, Ireland, Kosovo, the Netherlands, and Spain) and three sectors (construction, health, and ICT): generated by the project (WP2 to 4)

Objective 2: to adapt and integrate interventions to develop the multilevel MENTUPP intervention

Based on the systematic reviews and the Delphi study, existing interventions are adapted, and new interventions are developed. Interventions will target leaders and employees and may consist of training materials, campaign materials and online tools, and are to be used in nine countries (Albania, Australia, Finland, Germany, Hungary, Ireland, Kosovo, the Netherlands, and Spain) and three sectors (construction, health, ICT).

Responsible work packages: WP2 to 4

Data collected:

- Intervention materials on wellbeing, stress, burnout, and depressive symptoms: self-created materials
- Intervention materials on depressive disorders and comorbid anxiety: self-created materials
- Intervention materials on stigma reduction: self-created materials

Objective 3: to conduct a pilot assessing the MENTUPP intervention in SMEs in the construction, health and ICT sector

The interventions developed in the context of objective 2 are tested in nine countries (Albania, Australia, Finland, Germany, Hungary, Ireland, Kosovo, the Netherlands, and Spain). In each country, the interventions are tested in one sector as follows:

- Albania, Australia, and Ireland will test the intervention in the construction sector
- Hungary, Kosovo, and the Netherlands will test the intervention in the health sector
- Germany, Finland, and Spain will test the intervention in the ICT sector

Each country will recruit one SME in the sector as prescribed above. Hence, data will be collected from nine SMEs as follows:

- Three SMEs active in the construction sector: 1 SME in Albania, 1 SME in Australia, and 1 SME in Ireland
- Three SMEs active in the health sector: 1 SME in Hungary, 1 SME in Kosovo, and 1 SME in the Netherlands
- Three SMEs active in the ICT sector: 1 SME in Germany, 1 SME in Finland, and 1 SME in Spain

Responsible work packages: WP7 and 8

Data collected in the 9 SMEs:

- Mixed methods evaluations: self-created quantitative and qualitative data of leaders and employees collected via questionnaires and focus groups
- Descriptive and exploratory research: self-created quantitative data based on the user statistics of the MENTUPP Hub online platform
- Descriptive and exploratory research: self-created quantitative and qualitative data on the representativeness of the participating SMEs

Objective 4: to conduct a multi-country cluster randomised controlled trial to assess the effectiveness of the optimised MENTUPP intervention

The interventions tested in the context of objective 3 are further examined in the nine countries using a clustered randomised controlled trial (cRCT). In eight countries (Albania, Finland, Germany, Hungary, Ireland, Kosovo, the Netherlands, and Spain), the intervention is tested in the construction, health, and ICT sector. In Australia, the intervention is only tested in the construction sector. In total, 50 SMEs are recruited in the nine countries: Albania, Finland, Germany, Hungary, Ireland, Kosovo, the Netherlands, and Spain will each recruit 6 SMEs (2 SMEs active in construction, 2 SMEs active in health, and 2 SMEs active in ICT), whereas Australia will only recruit 2 SMEs active in construction. Accordingly, the 50 SMEs are allocated to either the intervention or control condition: one of the two SMEs within every sector and country is allocated to the intervention condition; the other SME is allocated to the control condition.

Responsible work packages: WP8 and 9

Data collected in the 50 SMEs are similar as in the pilot:

- Mixed methods evaluations: self-created quantitative and qualitative data collected via questionnaires and focus groups

- Descriptive and exploratory research: self-created quantitative data based on the user statistics of the MENTUPP Hub online platform
- Descriptive and exploratory research: self-created quantitative and qualitative data on the representativeness of the participating SMEs

Objective 5: to further optimise the MENTUPP intervention materials for wider replication post-cRCT

Based on the data collected in the context of objective 4, the developed materials are optimised so they can be used among a wider range of sectors.

Responsible work package: WP2 to 4

Data collected:

- Optimised intervention materials on wellbeing, stress, burnout, and depressive symptoms: self-created materials
- Optimised intervention materials on depressive disorders and comorbid anxiety: self-created materials
- Optimised intervention materials on stigma reduction: self-created materials

Objective 6: to promote the MENTUPP project and intervention to stakeholders

The MENTUPP materials and hands-on guidelines and recommendations on the effective implementation of the MENTUPP interventions are disseminated to a wide target audience (policymakers, unions, other SMEs among a wider range of occupational sectors).

Responsible work package: WP10

Data collected:

- Descriptive and exploratory research: quantitative and qualitative data on the communication and dissemination of the MENTUPP materials and interventions

4.2. Type, format, and origin of the collected data

The table below provides an overview of the 21 datasets that will be collected within the MENTUPP project, specifying name, description, type, origin, format, accessibility, size, collector, and objective of the data. The datasets collected in WP7 and WP9 will consist of pooled data collected in the nine intervention countries during the pilot test and the cRCT.

Table 1. Overview of the name, description, type, origin, format, accessibility, collector, and objective of the datasets.

No.	Name dataset	Description	Data type	Origin of the data	Data format	Open data	Size	WP	Objec-tive
1	SR_WP2	Three systematic reviews on interventions for wellbeing, stress, burnout, and depressive symptoms (one for each sector)	Literature review	Reuse of existing data	.docx and .xls files	Will be specified later	< 15 MB	2	1

2	SR_WP3	Systematic review on interventions for depressive disorders and comorbid anxiety	Literature review	Reuse of existing data	.docx and .xls files	Will be specified later	< 15 MB	3	1
3	SR_WP4	Systematic review on interventions for stigma reduction	Literature review	Reuse of existing data	.docx and .xls files	Will be specified later	< 15 MB	4	1
4	SR_WP5	Systematic review on barriers and facilitators of the implementation of mental health programs	Literature review	Reuse of existing data	.docx and .xls files	Will be specified later	< 15 MB	5	1
5	SC	Consultation of experts in the 9 countries (Delphi study) about existing interventions targeting wellbeing, stress, burnout, and depressive symptoms, depressive disorders, co-morbid anxiety, and de-stigmatisation of mental health, and the implementation of such interventions.	Qualitative and quantitative survey data	Generated by the project	.docx and .xls files	Will be specified later	< 10 MB	2-5	1
6	IM_WP2	Intervention materials on wellbeing, stress, burnout, and depressive symptoms	Will be specified later	Generated by the project	Will be specified later	Will be specified later	Will be specified later	2	2
7	IM_WP3	Intervention materials on depressive disorders and comorbid anxiety	Will be specified later	Generated by the project	Will be specified later	Will be specified later	Will be specified later	3	2
8	IM_WP4	Intervention materials on	Will be specified later	Generated by the project	Will be specified later	Will be specified later	Will be specified later	4	2

		stigma reduction							
9	SQ_WP7	Standardised questionnaires administered to employers and employees in 9 countries and 3 sectors during the pilot	Quantitative survey data	Generated by the project	.xls or .sav files	Will be specified later	< 15 MB	7&8	3
10	FG_WP7	Focus groups with employers and employees in 9 countries and 3 sectors during the pilot	Qualitative focus group data	Generated by the project	.docx or .nvivo files	Will be specified later	< 5 MB	7&8	3
11	US_WP7	User statistics of the Hub online platform during the pilot	Quantitative data	Generated by the project	.xls or .sav files	Will be specified later	< 10 MB	7&8	3
12	SME_WP7	Descriptive data on the SMEs participating in the pilot (size, family business or not, economic phase, turnover)	Quantitative data	Generated by the project	.xls or .sav files	Will be specified later	< 5 MB	7&8	3
13	SQ_WP9	Standardised questionnaires administered to employers and employees in 9 countries and 3 sectors during the cRCT	Quantitative survey data	Generated by the project	.xls or .sav files	Will be specified later	< 150 MB	8&9	4
14	FG_WP9	Focus groups with employers and employees in 9 countries and 3 sectors during the cRCT	Qualitative focus group data	Generated by the project	.docx or .nvivo files	Will be specified later	< 10 MB	8&9	4
15	US_WP9	User statistics of the Hub online platform during the cRCT	Quantitative data	Generated by the project	.xls or .sav files	Will be specified later	< 30 MB	8&9	4
16	SME_WP9	Descriptive data on the SMEs participating in the cRCT (size, family business or not, economic	Quantitative data	Generated by the project	.xls or .sav files	Will be specified later	< 30 MB	8&9	4

		phase, turnover)							
17	OIM_WP2	Optimised intervention materials on wellbeing, stress, burnout, and depressive symptoms	Will be specified later	Generated by the project	Will be specified later	Will be specified later	Will be specified later	2	5
18	OIM_WP3	Optimised intervention materials on depressive disorders and comorbid anxiety	Will be specified later	Generated by the project	Will be specified later	Will be specified later	Will be specified later	3	5
19	OIM_WP4	Optimised intervention materials on stigma reduction	Will be specified later	Generated by the project	Will be specified later	Will be specified later	Will be specified later	4	5
20	CD_WP7	Descriptive data on communication and dissemination during the pilot	Quantitative monitoring data	Generated by the project	.xls files	Will be specified later	< 5 MB	11	6
21	CD_WP9	Descriptive data on communication and dissemination during the cRCT	Quantitative monitoring data	Generated by the project	.xls files	Will be specified later	< 30 MB	11	6

To ensure long-term usability of the data, .xls files will eventually be transferred to .cvs files, .docx files to .rtf files, and .sav files to .por files.

4.3. Re-use of any existing data

The systematic reviews (SR_WP2, SR_WP3, SR_WP4, and SR_WP5) will rely on scientifically published papers in peer reviewed journals and publications in the grey literature. For all publications, regulations for ownership/copyright will be respected. All other data will be generated in the context of the current research project.

4.4. Expected size of the data

At this stage it is difficult to assess the total size of all datasets. Thus far, a rough estimation is provided in table 1. The expected size will be updated at two points in time: firstly, in month 24 when we have a precise view on the size of the data collected during the pilot and a second time in month 46 when the exact size of the data collected during the cRCT is known.

4.5. Data utility: to whom might the collected data be useful

The data will be used by present and future researchers within the research units of the consortium partners. Additionally, the results will be useful for other researchers as well. The relevance for others will largely depend on the specific datasets and the requests from potential users. Overall, we expect the collected data to be relevant for researchers focusing on mental health in the workplace and other related areas such as health and mental health in higher education or schools. They will be able to use our results to inform their own research.

5. Fair data

5.1. Making data findable, including provisions for metadata

Table 1 provides the name for each dataset. To ensure the findability further, a document on the metadata will be created specifying for each dataset the following information:

- Title: name of the dataset
- Unique identifier: DOI
- Creators: names and addresses of the people and organisations who created or contributed to the data collection
- Date of creation: key dates associated with the data, including project start and end date, and the period covered by the data
- Keywords: keywords
- Funder: the organisation that funded the research
- Rights: the intellectual property rights held for the data
- Language: language(s) of the intellectual content of the resource
- Location: information on the spatial coverage of the data
- Method: information on how the data was generated, including equipment or software used
- Conditions for access to the data

The datasets collected in WP7 and WP9 will consist of data coming from nine countries (trial sites). The site data are collected by nine different partners involved in WP7 and WP9. KU Leuven (lead of WP8) is responsible for aggregating and analysing the site data and thus will function as the central data centre of the research project. KU Leuven will make the datasets findable for other researchers by depositing them in the data repository platform Zenodo. In Zenodo, the data will receive a unique DOI (Digital Object Identifier), which will make the datasets detectable for others.

5.2. Making data openly accessible

MENTUPP participates in the pilot for open access (ORD pilot) adopting an open access policy for scientific publications and research data.

MENTUPP will ensure open access to all peer-reviewed scientific publications that relate to its results. Published articles or the final peer-reviewed manuscripts are deposited in the online repository platform Zenodo within six months after the manuscript has been accepted for publication. All other relevant information that is generated in the context of MENTUPP (leaflets, reports, intervention materials, etc.) will be made freely available on the project website. To guaranty security, textual materials will be made available in protected PDF files. The dissemination will be managed with respect for the intellectual property rights of the owner beneficiary.

Datasets generated by the MENTUPP consortium are made openly accessible as much as possible. However, when the privacy of participants cannot be guaranteed by accurate anonymization, the dataset is opened under very strict conditions only or remains completely closed. Decisions on which datasets will be openly accessible under which conditions are made later during the project and will be specified in the data sharing agreement. These decisions will be added to the DMP in month 24.

Openly accessible datasets and their associated metadata and codebooks will be stored online within the generic and EU supported Zenodo data repository platform (www.zenodo.org), where a MENTUPP community will be created, and where access to the data will be granted following data sharing agreements as agreed by the MENTUPP lead investigators and project partners.

5.3. Making data interoperable

The datasets will be transcribed and saved in standard data formats such as .docx, .xls, .sav and. nvivo. These formats can be accessed with common software tools used by most research institutes worldwide such as: Word, Excel, SPSS, and Nvivo. Therefore, no documentation about the software is needed to access the datasets. To ensure long-term and wide-spread usability of the data, datasets will be transferred to more basic formats (such as .csv, .rtf, and .por) so they can be easily imported to other software programs and exchange and re-use between researchers, institutions, organisations, and countries is facilitated.

Where appropriate core vocabulary is used to capture fundamental characteristics of people, businesses, and locations. However, for most data, no controlled vocabulary exists. Instead we will use vocabulary that is generally accepted and commonly understood in the research field. All variables in the datasets, will be labelled by making use of clear definitions. Additionally, for all datasets with quantitative data, a codebook is created specifying the content of the dataset: definition of each variable, response codes for each variable, codes used to indicate nonresponse and missing data, and exact questions and skip patterns that are used.

5.4. Increase data re-use (through clarifying licences)

To permit a wide re-use of the data, pseudonymised datasets (that were agreed to become openly accessible in the data sharing agreement) will be placed within the repository within six months after the project's end date and will be stored for five years so third parties can access, mine, exploit, reproduce and disseminate the data free of charge. As described in the previous sections, rich documentation on the data is provided as well: metadata and codebooks of datasets.

6. Allocation of resources

Data will be deposited in the free Zenodo online repository. Hence, there are no extra costs related to making the datasets open access. Long term preservation of the data will be the responsibility of the Zenodo online repository.

The lead investigators of KU Leuven (Prof. dr. Chantal Van Audenhove and dr. Evelien Coppens) are responsible for: developing and updating the DMP, monitoring the implementation of the DMP, and managing the multi-country MENTUPP datasets. The Data Protection Officers (DPO) of KU Leuven (Toon Boon) and UCC (Catriona O'Sullivan) are responsible for the data security and privacy protection. The contact details of the lead investigators and DPO are provided to the MENTUPP partners and all research participants.

7. Data security

7.1. Ordinal personal data and sensitive personal data

Within the context of MENTUPP, WP7 to 9 are involved in the collection of ordinary personal data as well as sensitive personal data (datasets SQ_WP7 and SQ_WP9 in table 1).

The following ordinary personal data are collected:

- Date of birth, gender, and ethnic origin of respondents filling out the questionnaires.
- Transcripts of focus groups. Audio recordings will be deleted as soon as the audio recordings are transcribed.

The following sensitive personal data are collected: data on mental wellbeing, burnout, stigmatising attitudes towards mental disorders, mental health literacy, functional disability, and productivity at work. These data will be collected relying on objective (measurable, quantifiable) parameters.

During the pilot and the cRCT, quantitative data of the same participants will be collected prior to and after implementation of the interventions. Data of respondents collected at baseline need to be linked to data of the same respondent at follow-up. Therefore, during every data collection round, a personal identification code is generated for each respondent based on the following personal information that they need to enter:

- the first two letters of the first name of your mother
- the first two letters of the first name of your father
- their day of birth (e.g., when born on October 9, one should enter 09)
- the number of brothers they have
- the number of sisters they have
- the first two letters of their place of birth

7.2. Data storage

Personal data will be stored at two levels:

- First, the research partners of WP7 and WP9 who are involved in collecting data in the nine implementation countries, are responsible for collecting and storing the data locally at their central storage facilities in a safe manner. These central server storage services provide daily automatic back-ups so the data will be stored safely. Personal data are stored in separate password protected files and will be saved for the entire duration of the project. Pseudonymised data will be stored until five years after the ending of the project. In each implementation country, access to the data will be limited to: (1) the lead investigator who conducts the day-to-day pilot and cRCT and is involved in data collection and data processing, and (2) the research officers who are appointed to support the lead investigator.

- Second, the data will be stored at the central storage facilities of KU Leuven (WP8) as this beneficiary is responsible for aggregating, processing, and analysing the multi-country datasets. Therefore, the lead investigators WP7 and WP9 (the nine implementation countries) will transfer the datasets to the central data centre of KU Leuven using Belnet Filesender. Importantly, all data relating to human research participants will already be pseudonymised by the lead investigators of the nine implementation countries prior to transmission to KU Leuven. Coding will remove personal identifiers and information. Instead, each subject will receive a

serial number. The decoding key – linking the participant to their serial number – will remain in the local storage centre of each implementation country (in accordance with GDPR and local ethics clearance). Further measures will be taken to eliminate the risk of identification of individual subjects in the pseudonymised multi-country dataset, for example by collapsing country of origin categories when there are a small number of individuals from one specific country. Afterwards, when the decoding key is not necessary anymore, it will be destroyed.

7.3. Data processing agreement

A data processing agreement is drafted between the EU partners which is a legally binding contract that states the rights and obligations of each party concerning the protection of personal data.

The MENTUPP consortium, however, includes four countries located outside the EU: Albania, Kosovo, Australia, and the US. The US is on the "white list" of third countries (outside the European Union) of the EU which means that they are considered to offer an adequate level of data protection. Hence, personal data can be shared without complicated agreements, subject to compliance with GDPR requirements (e.g. legal basis for processing, data security, etc.). Albania, Kosovo, and Australia are not on the “white list” and thus a more detailed data processing agreement with explicit guarantees is drafted for them.

7.4. Data transfer

Data will be transferred from the nine implementation countries to KU Leuven using Belnet Filesender which is a secure data transfer system.

Data will transfer from the nine implementation countries to KU Leuven and not the other way around. Transfer from EU countries to non-EU countries is currently not an issue. Also, transfer of data between the nine implementation countries is not intended. When intentions in that regard change in the future, this will be clearly documented in the data management plan.

8. Ethical aspects

In accordance with the Horizon 2020 Guidance on Ethics Self-Assessment, the partners in the nine implementation countries (WP7 and 9) will seek ethics approval for both the pilot study and the cRCT at their locally responsible ethics committees. The ethical approval for the pilot will be submitted in month 9 and include a trial protocol, associated standard operating procedures, information sheets and consent forms for implementation and evaluation of the MENTUPP intervention, and an overview of all processing of personal data. Within the consortium, one ethics application is drafted and used in the nine countries to receive ethics approval. The ethical approval for the cRCT will be submitted in month 24.

KU Leuven (the lead of WP8) is not involved in implementing interventions and collecting data but is only involved in accessing and analysing pseudonymised data. Therefore, a full ethical approval from the ethics committee is not necessary. For KU Leuven it is sufficient that the ethics committee does a privacy (GDPR) check. Like the nine implementation countries, the application for the privacy check of the pilot will be submitted in month 9 and the application for the privacy check of the cRCT in month 24.

All data collection and data processing will be conducted in concordance with national and local data protection regulations, and in accordance with the General Data Protection Regulation (GDPR, 2016). The MENTUPP project will ensure maximum compliance to GDPR by considering the seven founding data protection principles as described in table 2.

Table 2. Overview of the GDPR principles, their definition, and the measures taken to meet the requirements.

Principle	Definition	Measures
Lawfulness, fairness, and transparency	Data processing occurs in a transparent manner with respect for all applicable laws, regulations, and rules	– An information letter is prepared to inform participants in a transparent and comprehensible way about the research project and the way their personal data will be handled. – Participants are asked to give informed consent: (1) to participate in the study and (2) to process their personal data. Informed consent to process their personal data will include: ○ A clear statement on data storage and potential data re-use for similar purposes. ○ Specific consent to use the cumulative data for open research purposes and dissemination: presentations at conferences, publications in journals, and depositing part of the data (after accurate anonymisation) in an open repository at the end of the project. – Subjects will have the right to withdraw their consent at any time. They can withdraw consent for participation in the study. In that case the participant will no longer participate in the study and no additional data collection will take place. Any personal data already collected can, however, continue to be used for research purposes. In addition, subject can withdraw their consent for data processing. In that case, the processing of personal data that is already collected will no longer take place and the data will be removed for cumulative results. Also, no additional data collection will take place.
Purpose limitation	Data processing only occurs for the purpose of our research and is reasonable and proportionate to the purpose of our research	– All data collection and processing is limited to the purposes as outlined in the research project and as participants gave consent for. – Every researcher will take care not to collect data that are outside the scope of his work package and not directly linked to the research goals. – Data processing and data sharing requests outside the scope of the research will be carefully considered by the consortium.
Data minimization	Only data that is necessary for achieving our research objectives are collected and processed	– Only data that are relevant to answer the research questions and test the hypotheses are collected and processed.
Accuracy	Personal data is kept accurate and up to date	– Steps are taken to ensure that inaccurate personal data are erased or rectified without delay.
Storage limitation	The data are stored not longer than necessary for the current re-	– Personal data that will no longer be used for project purposes will be deleted as soon as possible. – Audio recordings of focus groups will be deleted as soon as they are transcribed.

	search or possible further analyses	– All pseudonymised data are stored for five years.
Integrity and confidentiality	The data are handled with confidentiality by taking measures to guarantee the confidentiality and integrity of the data	– For every dataset it is indicated whether it contains personal data or not. This will be the case for most data collected in WP7 and 9 by the nine implementation countries. – When the dataset contains personal data that needs to be kept confidential, the following guidelines are to be followed: o Every country stores the datasets in separate password protected files on a secured GDPR-compliant server that automatically generates backups at regular times (e.g. every 24 hours). o Access to the datasets is limited to authorized persons (data managers) who are responsible for the data and require access to accomplish their research activities. These data managers are the lead investigators and the research officers involved in the pilot (WP7) and the cRCT (WP9). o Personal data are anonymised as quickly as possible after its collection. When the data cannot be anonymised completely, it will be pseudo-anonymised as much as possible. o The personal identifier (the key between the pseudo-anonymised files and the list of participants) is stored securely on a separate physical location from the pseudo-anonymised datasets but should be accessible in a feasible way in case data subjects request to withdraw their data. The key is destroyed once it is not necessary anymore. o Copies of the datasets can only be stored in encrypted form on a password protected storage device. These copies must be deleted as soon as possible and cannot be shared with anyone outside the consortium without accurate and compliant authorisation. o When researchers keep datasets with personal identifiable data on their personal computer or on a separate hard drive for data analysis, they need to use BitLocker or FileVault for the encryption of the hard drive. o Data collected in physical form (questionnaires and informed consents in paper form) are stored in a restricted-access area to which only authorised staff has access. Once the data are digitised, the physical copies are securely destroyed. o Datasets can only be shared on the online repository in an encrypted form. o Sharing of data with other researchers will never include personal data (i.e. any data that can identify or potentially identify an individual) or links to personal

		data. o KU Leuven, that acts as the central data centre and is responsible for processing and analysing the data of the nine trial sites, only receives pseudonymised data containing a serial number instead of personal identifiers. o For the analyses, measures are taken to eliminate the risk of identification of individual subjects. o In reports, peer reviewed papers and presentations, pseudonymised data are only released in aggregated form.
Accountability	Actions are taken by the data controller to ensure that all partners comply with the GDPR principles	− All necessary activities concerning the data management are documented in the DMP and this document is kept up to date. − All consortium partners are requested to read the DMP carefully and comply to the conditions listed in the DMP. − Partners are informed on relevant changes in the DMP. − The most recent version of the DMP is made available for all partners at any time by placing it on the share point. − When necessary, a training or webinar is developed on how to act in accordance to the DMP. − At the country level, two data managers are appointed (the lead investigator and the researcher officer) that are responsible for the protection of the datasets within their trial site. − At the project level, the project coordinator of MENTUPP and the lead of WP8 are responsible for accurate data management within the project by all consortium partners. They will regularly check whether consortium partners follow the guidelines. Difficulties and/or improper management of the data will be flagged and addressed as soon as possible. − All persons with access to the identifiable, non-anonymised personal data need to sign a confidentiality agreement (data protection contract). − Access to the personal datasets can be restricted or revoked when persons are not complying to the guidelines or when their contract is terminated.