Funded by
the European Union

ADVANCE

MENTAL HEALTH RESEARCH DONE DIFFERENTLY

Addressing mental health vulnerabilities from adolescence to older age:

innovating prevention science for times of change

Project No.

101080323

D8.1 Ethical Plan

December 2023

Zentralinstitut für Seelische Gesundheit

ISPUP INSTITUTO DE SAÚDE PÚBLICA DA UNIVERSIDADE DO PORTO

DET KGL. BIBLIOTEK

VU VRIJE UNIVERSITEIT AMSTERDAM

UNIVERSITY OF COPENHAGEN

UNIVERSITÄTSKLINIKUM HEIDELBERG

UNIVERSITÉ DE GENÈVE

UNIVERSITÀ di VERONA

UNIVERSITY OF TURKU

Vilnius University

M·H·E Mental Health Europe

World Health Organization

Ethics Plan

Document Type (nature)	Report
Deliverable No.	8.1
Work package No.	8
Deadline	Due M6
Actual date of submission:	22 December 2023
Responsible Beneficiary	Lead: UCPH Contributors: MHE, WHO, ISPUP, VU, CIMH, VUA, UNIVR, UNIGE, UKHD, UTU
Author(s)	Wietse Anton Tol (UCPH), Joyce Anne Quinto (UCPH), Falco Hüser (KB)
Publicity level	Public
Short description	Ethical plan to serve as an umbrella ethics guide for submitting to institutional review boards

History			
Version	**Date**	**Modification**	**Author**
0.1	10.11.2023	Initial draft	Wietse Anton Tol (UCPH), Joyce Anne Quinto (UCPH)
0.2	23.11.2023	Feedback loop - KB and UCPH	Falco Hüser (KB), Wietse Anton Tol (UCPH), Joyce Anne Quinto (UCPH)
0.3	15.12. 2023	Integration of feedback from all partners	ALL
1.0	20.12 2023	Final strategy document for submission	Wietse Anton Tol (UCPH)

Document Review & Approval		
Reviewer	**Partner ID/ Acronym**	**Date of report approval**
Maria Marti Castaner	UCPH	20 December 2023
Falco Hüser	KB	19 December 2023
Maritta Välimäki	UTU	20 December 2023
Ulrich Reininghaus	CIMH	21 December 2023
Manuela De Allegri	UKHD	20 December 2023
Corrado Barbui	UNIVR	19 December 2023
Evaldas Kazlauskas	VU	19 December 2023
Raquel Teixeira	ISPUP	20 December 2023
Ken Carswell	WHO	15 December 2023

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency. Neither the European Union nor the granting authority can be held responsible for them.

Table of Contents

Executive summary

The D8.1 Ethics Plan sets out guidelines for ethical compliance during the conduct of all tasks under the ADVANCE project. This document includes a guide on the establishment and selection of members for the ADVANCE Ethics and Data Advisory Board (EDAB), management of ethical issues, and management of sensitive research data (aligned with the D8.4 Data Management Plan).

This document, along with the Data Management Plan, will serve as umbrella documents that will be followed when partners draft and submit their own research protocol to their local institutional review boards.

1. Introduction

The ADVANCE consortium is dedicated to accomplishing the goal of developing a public-facing, openly accessible resource package that will include guidance and methodologies required to ensure that effective preventive and promotive mental health programmes can be developed, adapted, implemented, assessed, and scaled.

To achieve this, ADVANCE will conduct six evaluation studies of preventive and promotive mental health intervention and implementation strategies (hereafter 'intervention studies'): Five randomized controlled trials and one (uncontrolled) cohort implementation study. These studies are aimed at evaluating the benefits of evidence-based, scalable mental health promotion and prevention interventions with regard to: (1) individual benefits (e.g., wellbeing, psychological distress); (2) stigma-related outcomes; and (3) implementation outcomes (i.e.., extent to which interventions are rolled out, at a systems-level, in real-world service delivery settings). The intervention studies are preceded by a co-creation phase (to finalize intervention scenarios) and a research phase aimed at adapting interventions to end-user preferences. Following the completion of the intervention studies, scaling strategies will be developed based on findings from the intervention studies.

This Ethics Plan aims to support the consortium partners by providing an overview of issues and guidelines in conducting such intervention studies within the ADVANCE project. It sets out basic principles and responsibilities set out by the European Commission for European-funded projects.

2. Management of ethical issues

2.1. EC Ethics requirements

The EC perceives 'ethics' as:

> *"…including questions of legal and regulatory compliance as well as a branch of philosophy. It is part of a process of 'governance'. In this vein, the EC document "A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research" asserts that ethics is a key oversight mechanism to ensure that EU funded research is not misused."*[1]

ADVANCE is committed to conduct research with the highest ethical standard and the applicable EU, international and national law on ethical principles, including the EU Charter of Fundamental Rights, as well as the European Convention for the Protection of Human Rights and Fundamental Freedoms and its Supplementary Protocols. ADVANCE also commits to ensuring that it respects basic EU values (i.e., respect for human dignity, freedom, democracy, equality, the rule of law and human rights, including the rights of minorities).

ADVANCE will ensure to *"pay particular attention to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of persons, the right to non-discrimination, the need to ensure protection of the environment and high levels of human health protection"*, as is stipulated in Annex 5 of the ADVANCE Grant Agreement.

ADVANCE also upholds research integrity based on the European Code of Conduct for Research Integrity[2].

With the implementation of this Ethics Plan, ADVANCE will ensure that persons carrying out research tasks follow the good research practices including ensuring, where possible, openness, reproducibility and traceability and refrain from the research integrity violations described in the Code of Conduct.

[1] 1 Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects. https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/ethics-guide-advisors_en.pdf
[2] European Code of Conduct for Research Integrity of ALLEA (All European Academies).

2.2. Ethical and Data Advisory Board

The Ethics and Data Advisory Board (EDAB) comprises ethics and data experts advising ADVANCE project partners. Their role is to enhance, build upon, and complement existing oversight regimes by ethical and legal authorities in partner institutions and countries. The EDAB will monitor and provide expert advice on data management and all ethical issues that may arise within or as a result of ADVANCE.

The EDAB will be required to specifically monitor three main aspects:

(1) recruitment, inclusion and exclusion criteria, and informed consent procedures;

(2) data management (protection and privacy); and

(3) vulnerability of the population.

For each of these aspects, the EDAB will be required to give **advice** and **guidance** on:

- approval requirements by the ethics committees of each country;
- feedback received by the ethics committees of each country and suggestions for improvement;
- development and implementation of the Data Management Plan (data protection and privacy i.e., adherence to the GDPR.);
- dissemination and preservation of research data;
- development of Standard Operating Procedures (SOPs) for participant enrolment and for gathering informed consent, including the establishment of Data Safety Management Boards within each study site (as per applicable national and institutional regulations);
- implementation of SOPs for participant enrolment and for gathering informed consent;
- any specific ethical question arising during the project (e.g. concerning serious adverse events in the clinical trials);
- any issues concerning safety, rights, and wellbeing of study participants; and
- any issues concerning the relevant legal framework and regulatory requirements in the countries involved.

Considering ethical issues in ADVANCE not only improves research and innovation quality but also protects participants and researchers, increases social impact, upholds research integrity, aligns research with societal needs, and facilitates the societal acceptance of research outcomes. High ethical standards are key to earning public trust in the project.

The EDAB will advise on its own initiative, as well as upon request. The EDAB will work closely with Work Package 8 (led by UCPH).

From an ethics management perspective, the key actors of this Advisory Board are the Ethics Advisor, Data Management Advisor, and the Members.

- The Ethics Advisor will monitor and report the status of the project with respect to ethical compliance and the ethical implications of innovation. The Ethics Advisor will lead the EDAB.
- The Data Management Advisor (KB) will be responsible for decisions about the protection and management of data gathered during the project or use within the project if gathered previously and advise on the safe, secure and compliant management and use of real data.
- The role of the Members of EDAB is to review deliverables from the ethics point of view and provide ad hoc consultancy on ethical issues that emerge during the ADVANCE project. The EDAB provides independent input to the Consortium on ethical compliance based on the reports and project meetings. Their comments will be included unabridged in the periodic ethics reports. ADVANCE will appoint 1-3 Members of EDAB.

No compensation for the members of the EDAB is provided for in the ADVANCE budget. For this reason, the EDAB's role will be limited to the provision of advice upon request on specific issues as they emerge and examination of controversial questions. Monitoring activities are excluded from the responsibilities of EDAB, since they are the responsibility of the WP8 team.

An annual meeting will be organized online with the presence of the Coordinator.

We estimate the EDAB team will allocate a minimum 10 days during the whole project years 2023-2028.

A Memorandum of Understanding (MOU) will be drafted to clearly define the mandate of the EDAB and regulate the interactions with the

consortium. The MOU will include information on the format and frequency of meetings and the reporting functions of the EDAB. The MOU will make it clear that the EDAB will diligently monitor the aims, objectives, methodology and implications of the research to ensure that it conforms to the highest ethical standards, ensuring that the researchers, the Commission, and the general public are not exposed, by the work of the project, to activities that would be considered to be ethically unacceptable[3]. The Coordinator will also ensure that a non-disclosure agreement is executed between all Parties and each EDAB member.

2.3. Appointment of EDAB members

According to the EU guidelines, it is essential that members of the EDAB are external to the project and to the host institution, as well as totally independent and free from any conflict of interest. However, the Danish Royal Library (KB) has been included in the project to fulfill such external view of the clinical trials/interventions and research phases that ADVANCE will conduct. ADVANCE's EDAB will therefore include internal and external members, with KB playing as ADVANCE's official Data Management Advisor.

The Ethics Advisor and Members, on the other hand, will be selected from external institutions (academic, policy, industry, and end-users) using these criteria:

- Some members should possess a background in **science or research**, qualifying them to assess specific research activities and the proposed research's acceptability in terms of institutional commitments, regulations, applicable law, and professional conduct standards.
- To ensure a balanced review, some members should have **non-scientific backgrounds**, including community representatives, religious or community leaders, or former study participants. These diverse members contribute insights into how the research may impact the community. It is crucial to afford these non-scientific members the same level of respect as their scientific counterparts.

[3] European Commission. Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects. Revised Edition. 2013. Available from https://allea.org/wp-content/uploads/2023/06/European-Code-of-Conduct-Revised-Edition-2023.pdf

- Additionally, promoting **diversity** in gender, age, and ethnic and cultural backgrounds among ethics committee members enhances the overall balance and effectiveness of research reviews.

EDAB will be formally established by M8.

2.4. In case of scientific misconduct

ADVANCE consortium members acknowledge potential ethical challenges and reject all forms of scientific misconduct. ADVANCE members are dedicated to upholding the fundamental principles of research integrity outlined in the revised European Code of Conduct for Research Integrity (ALLEA, 2023), irrespective of the research location:

- **Reliability** in ensuring the quality of research, reflected in the design, the methodology, the analysis, and the use of resources.
- **Honesty** in developing, undertaking, reviewing, reporting, and communicating research in a transparent, fair, full and unbiased way.
- **Respect** for colleagues, research participants, society, ecosystems, cultural heritage, and the environment.
- **Accountability** for the research from idea to publication, for its management and organisation, for training, supervision, and mentoring, and for its wider impacts.
- In addition to the ALLEA principles, we also strongly emphasize **openness** and making sure that our scientific research results are available to all levels of the society.

ADVANCE will strive to prevent any breaches of research integrity. Research misconduct encompasses fabrication of results, falsification of data or records, plagiarism, or piracy, failing to acknowledge authorship, misleading reporting of study results, sabotaging the work of other scientists, etc.

In the event of misconduct related to ADVANCE activities, it will be addressed locally in accordance with local regulations, following the principle of subsidiarity. Consortium partners will promptly inform the EDAB and the Coordinator of any such misconduct, providing regular updates on the local process.

2.5. Ethical clearance

ADVANCE will ensure to comply with additional requirements formulated by ethics boards (including after checks, reviews, or audits). Obtaining ethical clearances and/or other mandatory documents for conduct of research will be done and implemented according to the standards and regulations in the local context of the WPs where the study will be conducted. This includes securing approvals from one to two national or local ethics committees and other bodies, such as institutional review boards at partner universities.

As this process can be time consuming, intervention study teams are encouraged to start the process at the earliest time possible.

In some cases (i.e., institutions), requiring ethical clearances can be expensive – this, of course, has been considered during the proposal stage. WP Teams can opt to submit one protocol for the whole 5-year study, provided that the teams have considered the content of this umbrella Ethics Plan.

Ethics submissions will be kept on file by WP leads and will be submitted upon request by the Coordinator to the granting authority. If they are not in English, they will be submitted together with an English summary, which shows that the documents cover the action tasks in question and includes the conclusions of the committee or authority concerned (if any).

Table 1 summarizes the WPs planned procedures related to the conduct of ethical clinical studies. The full information on clinical studies is provided extensively in Section 5 of the Grant Agreement.

Table 1. Short summary of planned procedures related to conduct of ethical clinical study in each country (full details can be found in Section 5 of the Grant Agreement)

Intervention study	Regulatory and health technology assessment bodies OR Clinical efficacy, safety, and methodological guidelines to adhere to	Access to regulatory expertise	Additional notes for local clinical study protocol
WP2: Evaluation of EMIcompass with youth affected by climate change in Germany	- Clinical Trials Regulation (Regulation EU No 536/2014) as 'clinical trial' and as an 'other clinical investigation' - Digital components of the intervention system have been developed and will be optimized in line with the prevailing regulatory requirements (incl. MDR 2017/745, ISO 14971 (risk management), IEC 62304 (software life cycle), IEC 62366 (usability) standards, ISO 14155 (GCP), ISO 13485 (quality management) and, in line with this, the proposed study will be conducted as an 'other clinical investigation' (MDR, §82). - Guidelines for Ethical Review: https://etikostarnyba.lt/wp-content/uploads/2022/07/Guidelines-for-Ethical-Review-incl-amendments.pdf	- EDAB - Federal Institute for Drugs and Medical Devices (BfArM) in Germany - CIMH Data Monitoring and Ethics Committee (DMEC)	-
WP2 (VU): Evaluating Scalable Technology for Adolescents and Youth to Reduce Stress (STARS) for socio-economically disadvantages young adults in Lithuania	- National and EU regulations - Guidelines for Ethical Review by the Office of the Ombudsperson for Academic Ethics and Procedures of the republic of Lithuania: https://etikostarnyba.lt/wp-content/uploads/2022/07/Guidelines-for-Ethical-Review-incl-amendments.pdf - WHO Ethics Review Committee: https://cdn.who.int/media/docs/default-source/documents/ethics/who-erc-submission-and-exemption-advice.pdf	- EDAB - Ethics Committee of VU	-
WP3 (VUA): A sequential cluster-randomized controlled trial examining the effectiveness of WHOs manager training for mental health (MTM) and a stress management skills intervention for	- Declaration of Helsinki. Medical Research Involving Human Subjects. - ICH E6 Guideline for Good Clinical Practice - Wet Medisch-Wetenschappelijk Onderzoek met Mensen (WMO). - FAIR Data Management - CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. - Gamble C, Krishan A, Stocken D, et al. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials.	- EDAB - Medical Ethics Committee of the VU Medical Center, Amsterdam, the Netherlands	Detailed protocol for the trials (pilot study and sequential RCTs (RCT1 and RCT2) to be submitted to the Medical Ethics Committee of the VU Medical Center, Amsterdam, the Netherlands, for approval.

Intervention study	Regulatory and health technology assessment bodies OR Clinical efficacy, safety, and methodological guidelines to adhere to	Access to regulatory expertise	Additional notes for local clinical study protocol
employees (Doing What Matters in times of stress; DWM) on manager- and employee outcomes in small and medium enterprises in the Netherlands.	- Statistical principles for clinical trials. International Conference on Harmonisation E9 Expert Working Group. - Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials; International Council for Harmonisation; Guidance for Industry; - WHO Ethics Review Committee: https://cdn.who.int/media/docs/default-source/documents/ethics/who-erc-submission-and-exemption-advice.pdf - The Netherlands: "Netherlands Code of Conduct for Research Integrity": https://doi.org/10.17026/dans-2cj-nvwu		The approved trial protocol will be registered in a dedicated website (i.e., clinicaltrials.gov). The implementation trials will not imply testing any pharmacological therapy but phase two of the sequential RCT involves employees with psychological distress.
WP4 (UCPH): Integrating Self Help Plus (SH+) into social integration programming for migrants in Denmark: An implementation study.	- Declaration of Helsinki. Medical Research Involving Human Subjects - European Commission. Guidance note - Research on refugees and asylum seekers - ICH E6 Guideline for Good Clinical Practice: https://www.ich.org/page/efficacy-guideline - European Commission. Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects. - British Psychological Society. Conducting research with people not having the capacity to consent to their participation. A practical guide for researchers. - Denmark: "The Danish Code of Conduct for Research Integrity": https://ufm.dk/en/publications/2014/the-danish-code-of-conduct-for-research-integrity	- EDAB - Regulatory expertise through the municipalities, as they are regulators for mental health and social services in Denmark.	The study protocol, statistical analysis plan, and data management plan will be developed during the course of the ADVANCE project as stand-alone documents.
WP4 (UNIVR): Comparing the benefits of in-person and online delivery of evidence-based stress management interventions with migrants in Italy	- Declaration of Helsinki. Medical Research Involving Human Subjects - European Commission. Guidance note - Research on refugees and asylum seekers - ICH E6 Guideline for Good Clinical Practice: https://allea.org/code-of-conduct/	- EDAB - UNIVR Ethics Committee	Involvement of end users requires a signature for informed consent, along with an explanation of the project characteristics. Informed consent is signed only once at the beginning of the study.

Intervention study	Regulatory and health technology assessment bodies OR Clinical efficacy, safety, and methodological guidelines to adhere to	Access to regulatory expertise	Additional notes for local clinical study protocol
	- European Commission. Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects. - British Psychological Society. Conducting research with people not having the capacity to consent to their participation. A practical guide for researchers. - Office of the Federal Register, National Archives and Records Administration. (2021, May 12). 86 FR 26047 - E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials; International Council for Harmonisation; Guidance for Industry;		Ethics committee provided a 10-page template (project overview, project descriptive details, participant information, risk management, consent, and anonymity and privacy of personal data).
WP5 ADVANCE WP5 (UNIGE): Evaluating combined cognitive training and stress management for older adults in Switzerland	- National and EU regulations apply - University of Geneva "Code of ethics and professional conduct" https://www.unige.ch/ethique/charter	- EDAB - UNIGE research office and an Ethics Committee	-

3. Ethical guidelines and procedures

3.1. Data collection

ADVANCE carefully selected target groups, from youth to old age, to address the most critical mental health risks facing Europe in our age:

- socio-economically disadvantaged young adults (18-24) (Lithuania) (WP2);
- youth (12-25) affected by climate change (Germany) (WP2);
- adults in digitalized work settings (the Netherlands) (WP3);
- adult migrants (Denmark, Italy) (WP4); and
- older adults (Switzerland) (WP5).

These specific groups were selected because there is evidence that these groups are at particular risk for mental health concerns, and thus the most appropriate focus for mental health promotion and prevention interventions aimed at reducing risks.

In all studies, inclusion criteria include screening on the basis of exposure to risks and experiencing moderate levels of psychological distress, so that interventions target those most at risk, but exclude people with mental disorders in need of treatment (those participants will be referred to existing clinical mental health services).

We will collect **personal data** in the form of:

1. **qualitative data** (e.g., semi-structured interviews to elicit perspectives on experiences with an intervention, or barriers to participation in an intervention) and
2. **quantitative data** (e.g., structured survey questionnaires asking about experienced levels of psychological distress, subjective wellbeing, experiences of stigma, and economic costs associated with participating in prevention interventions).

The specific types of data that ADVANCE will collect is explained extensively in D8.4 Data Management Plan.

3.2. Participant identification, recruitment, and management

Broadly speaking, ADVANCE will include three different types of participants:

- volunteers in the co-creation activities and development of scaling strategies (e.g., end-users, policymakers, and providers guiding activities and giving inputs throughout the project);
- those who will receive the trialed interventions; and
- participants in trial control conditions.

3.2.1. Volunteers in the co-creation activities

Stakeholders in co-creation will primarily contribute non-human subjects' relevant expertise, following rigorous ethical procedures, including informed consent and anonymity. Special emphasis will be placed on promoting equitable participation and ensuring a voice for all, addressing potential power differentials.

3.2.2. Recipients of trialed interventions

We anticipate minimal negative impact on intervention recipients. We base this expectation on several factors: the evaluation of non-invasive, evidence-based interventions with a low-risk profile and strong evidence for improving mental health; a comprehensive co-creation process using human-centered design activities to tailor interventions to end-user preferences; feasibility studies assessing the acceptability of research and intervention protocols with smaller participant groups and ongoing consultation to address any inadvertent negative impact; the use of validated screening tools for psychological distress; thorough training for intervention and research staff to manage potential participant distress; and the incorporation of stigma prevention strategies at all stages, including the use of digital interventions with no AI components that pose no risk to human rights or values.

3.2.3. Participants in trial control conditions

Participants in all control conditions for the five randomized controlled trials (excluding the uncontrolled implementation study) will receive Enhanced Care As Usual (ECAU), aligned with World Health Organization ethics requirements. ECAU will adapt to the specific intervention being tested and customary care procedures in different settings. It will encompass standard care, such as psychoeducation delivered by community health or social providers, enhanced with evidence-based stress management strategies, and guidance on accessing and utilizing resources. Importantly, there is no literature demonstrating harm associated with psychoeducation for individuals at risk of mental health issues and psychological distress.

3.3. Risks and Safety Measures

3.3.1. Potential Risks

Given our specific focus on assessing mental health interventions for vulnerable populations, we will proactively address and manage potential risks of negative impact:

Stigma

First, there is a potential risk of stigma commonly associated with mental health interventions, even in promotion and prevention interventions where disorder-related terminology is not explicitly used (e.g., unlike clinical treatments for specific mental disorders). As part of our co-creation activities, we will pay specific attention to identifying which elements of our intervention scenarios (e.g., in terms of recruitment strategies, or words used) are associated with risk for stigma, so that we can avoid them. We will do the same during the human centered design activities aimed at adapting interventions to end-user preferences; as well as the feasibility studies prior to randomized controlled trials.

Vulnerability

Secondly, regarding research participants from vulnerable populations, there may be risks associated with singling out individuals based on factors like migrant status, socio-economic disadvantage, or age. Since most interventions are online, minimizing this risk, any in-person activities, such as SH+ workshops, will occur in safe, neutral, private spaces chosen in consultation with end-users. Vulnerable populations also face a higher likelihood of adverse events, whether or not related to study participation, necessitating detailed protocols for reporting and the EDAB to review all adverse and serious adverse events.

3.3.2. Ethical Procedures

Communication training for staff

ADVANCE will carefully train all research and intervention staff in communication skills (using psychological first aid principles) and all appropriate ethical procedures.

Where this risk exists, ADVANCE will train staff in the management of people who experience distress because of participation in research interviews or interventions. ADVANCE experts' wide experience shows that most people appreciate speaking of feelings of distress, as this is not always possible within the family or community setting, and so experience relief from participation in interviews.

Informed consent

We will follow the highest ethical standards following EU and national ethical research guidelines in each country, including ethical procedures around anonymity (e.g., use of non-recognizable participant codes), written informed consent (assent in case of adolescents, additional oral assistance for participants with visual impairments or limited literacy), written information about the studies, and data safety.

Confidentiality

Every participant has the right to maintain confidentiality, ensuring that only the researcher is aware of their involvement. Typically, data in the final report will be anonymized, preventing any attribution to individual participants. Procedures for data collection (including personally sensitive data, e.g. about ethnicity, SES, emotional states), storage, protection, retention, and destruction will comply with national and EU legislation including Article 29 Workgroup paper no WP131 on "The processing of personal data relating to health in electronic health records".

Emergency management

In exceptional cases where severe distress occurs or someone expresses a possible risk of imminent risk of suicide , abuse, or other serious protection or safeguarding concerns, we will put in place emergency procedures (e.g., back-up clinical assistance arranged prior to interviews, referral pathways clear and approached before interviews, training in self-harm and risk management) that we have extensive experience in applying.

Advisory Group

ADVANCE will install EDAB at the earliest possible to ensure ethical oversight and data safety and provide an independent external overview of the implementation of our ethical protocols, and review and approve of procedures when handling participants who may experience adverse events and seriously adverse events.

The activities in Switzerland are all allowed in EU countries.

3.4. Special categories of data

Data collection within ADVANCE will strictly comply with EC regulations and the legislation of individual Member States and Associated Countries. Specific cases for data collection are outlined as follows:

- **The collection of personal, non-sensitive data within the workshops /interviews/ questionnaires:** collection of data will only entail the collection of personal, non-sensitive data.
- **Written and audio/visual documentation of the workshops and/or interviews:** participants of the project's interviews and workshops will be debriefed and fully notified of data collection activities, including audio/visual documentation. Consent forms will be made available to the participants. Volunteers will be able to withdraw from these activities at any given time.

Table 2. Overview of ADVANCE data types

Data collection phase	Types of Data
Problem analysis and co-creation (Work Package 1)	• Interviews, audio recordings and observation notes from focus-group workshops (face-to-face or online) with SAG groups in Finland. • Results from desk reviews of academic and grey literature in seven countries (Lithuania, Germany, The Netherlands, Denmark, Italy, Switzerland and Finland), collected in spreadsheets following a common template. • Results from two rounds of Delphi surveys with SAG and research team members in the six countries with intervention studies and in Finland (as part of the scaling strategy development), collected through online questionnaires, anonymized and exported as spreadsheets. • Transcriptions of video-/audio-recordings from two rounds of scenario-based workshops with SAG members in the six countries with intervention studies. • Audio recordings and meeting notes from consultation meetings with SAG members in seven countries regarding the development of intervention studies and scaling strategy. • Documentation of co-creation process in seven countries in local language. • Results from a national survey in Finland, collected through the Webropol Survey & Reporting tool. Surveys contain quantitative data (rankings on a pre-defined scale) and qualitative data (free text answers to open questions).
Intervention studies (Work Packages 2-5)	Each intervention study will collect:

Data collection phase	Types of Data
	• Quantitative data from e.g. surveys, self-reporting forms, structured interviews and/or behavioral tests. • Context information, such as demographic data, participation data and performance data. • Qualitative data in the form of interview recordings and transcriptions.
Cross-cutting intervention study activities (Work Package 6)	Each intervention study will gather: • Documentation of participant responses and semi-structured interviews in various forms, such as observation logs, facilitator notes, interview guides, audio recordings etc. (for the adaptation process and prototype content reviews). • Data for the economic evaluation, including data on intervention costs; CSRI data on use of health care, social care, judicial care and informal care, EQ-5D-5L data on health outcomes of the interventions.

3.5. Data minimization and protection

Data minimization means that personal data shall be adequate, relevant, and limited to what is necessary in relation to the purpose for which they are processed. In ADVANCE, the collection of personal data will be kept to a minimum, with only the collection of information that is needed to fulfil the objectives of the ADVANCE project.

The retention and dissemination of data within ADVANCE are outlined in the Data Management Plan. Generally, data will be aggregated and anonymized promptly in line with research activities. Raw data from the intervention studies that may contain personal, sensitive, or confidential information and will not be deposited in Zenodo but archived at the institution that carried out the respective study. Access to these data will require approval according to applicable legislation and ethical procedures (with details to be described for each intervention site individually).

Whenever possible, data that needs to be shared with other consortium members will be fully anonymized. If there is a need to share personal (including pseudonymized) information with other consortium members, the involved parties will establish all necessary agreements (according to institutional and national regulations and procedures). This might in particular be the case for

data from co-creation activities (shared with ISPUP) and the data for the economic evaluations (shared with UKHD).

ADVANCE will employ necessary security measures to prevent unauthorized use of personal data, with specifics provided to the EC in the Data Management Plan (D8.4) and Ethics Plan (this document). Consortium members may have internal regulations on ethics, privacy, and data protection, which should be observed and communicated to the Coordinator and the Data Management Advisor as applicable.

The project's data management advisor from the Royal Danish Library will coordinate and oversee this task.

4. Conclusion

The Ethics Plan is an important part of European research initiatives such as ADVANCE as it enables accountability, encourage mindful approach to ethical research, and assists partners with the determining and planning of practical aspects of research throughout the project.

As a living document, the Ethics Plan sets out guidelines for ethical implementation of research activities and the ethical management of research data, conduct of data collection, as well as overall conduct of the whole research process. However, written on a broad ethical term, this Ethics Plan aims to support the consortium partners in recognizing and understanding basic principles and responsibilities to the EC regulation on research ethics.

This plan should be revised and updated as needed to reflect research developments in ADVANCE.