WORKINGAGE

Smart Working Environments for All Ages

D2.6 Intervention Protocol

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WP2 – User Centric Design

D2.6 – Intervention Protocol

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Acronyms and Terminology

The following table reports the acronyms used in this deliverable.

Term	Definition
HCI	Human Computer Interaction
KPI	Key Performance Indicator

Executive Summary

This deliverable is one of the outputs of the project task "T2.5 DEFINITION OF PILOT TESTS", whose main objective is to address the specifications of the pilot applications to be deployed.

In particular, D2.6 specifies guidelines for the definition of interventions on participants (which will be designed in WP3 - Task 3.4) and provides an intervention protocol template that will be at the basis of the operational intervention manual in WP9 (Task 9.1).

Intervention protocols allow researchers conducting research with subjects that will receive one or more interventions and guarantee that the researchers can evaluate their effects. The protocol also includes ethical issues that have to be taken into account during the pilot tests and, in particular, for the interventions.

This document integrates and is based on deliverable D2.5 on "Field Test Strategy", which specifies time schedules, description of samples of workers of the pilots that will be carried out at the companies, testing approaches and logistics and management aspects.

It is structured as follows:

- Section 1 introduces the goals of the intervention protocol and clarifies how the document is related to the other WPs;
- Section 2 reports the intervention protocol design; in this first version (the final version will be delivered at M16), the document lists the requirements that need to be taken into account by other WPs in order to carry out all the activities of the pilot tests in WP9;
- Section 3 reports a draft of the intervention protocol template.

Table of Contents

1 Introduction

1.1 Goals of the Intervention Protocol

The intervention protocol aims at clarifying pilot studies requirements and setting up the condition and procedures for the different planned tests aiming to develop, implement and validate the WA change behaviour model.

It can guide the researchers and the companies during the pilot studies, so that researchers can conduct their research with subjects that will receive one or more interventions and later can evaluate their effects.

Since the research involves human subjects, the protocol includes also ethical and safety aspects.

The *WA intervention protocol* is inspired by the Intervention Mapping protocol proposed in the literature by Bartholomew [1][2]: it was proposed in the context of health promotion programmes and is based both on empirical data and on theory; it is a five step procedure preceded by a step for needs assessment.

The five steps include: 1)the definition of performance and change objectives based upon scientific analyses of health problems and problem causing factors; 2) the selection of theory-based intervention methods and practical applications to change (determinants of) health-related behaviour; 3) the production of program components, design and production; 4) the anticipation of program adoption, implementation and sustainability; 5) and the anticipation of process and effect evaluation.

The needs assessment is based on the PRECEDE-PROCEED model [3]: this model considers people's quality of live concerns, their health problems, the behavioural and environment factors. The objectives of the health promotion programs are both at the individual level (improving the behaviour of the single person), but may affect also the organizational level (e.g., the organization acknowledges the benefits of a behavioural change and recommends the program to the whole organization), and possibly at the community level, thus going beyond the organization and involving, for example, families, a territory etc.

The WA intervention protocol takes into account the peculiar characteristics of the WA tools, able to (automatically) monitor behaviours before and after the interventions.

1.2 Main Relationships with other WPs

The present deliverable is strictly bound to D2.5 "Field Test Strategy", which describes the general procedure for the pilot tests. Therefore, it refers to D2.5 for all the aspects related to pilot tests organization (population characteristics, time schedule, etc.).

It provides guidelines and requirements to:

- WP3, in particular for the definition of intervention measures to be adopted at the different pilot sites (in particular, to D3.4 "Intervention Measures Report");
- WP4, where WA Tools modules will be developed;
- WP7, dealing with ethical, security and privacy issues;
- WP9, where in-lab and pilot tests will be performed.

D2.6 version 1 will be refined at M16 with the inputs from WP3, WP4 and WP7.

It will provide basic input to WP9 for the definition of the "Pilot Operational Manual" (D9.1) that will describe in detail the pilot application, the documents to be used during the pilot tests (e.g., informal consent, questionnaires, etc.), user recruitment rules at each pilot site, performance metrics and their assessment procedures.

Figure 1 depicts the interrelationships between D2.6 and other WPs.

1.3 WorkingAge Pilot Tests

The WA Intervention protocol represents the operational part describing the procedure for the pilot studies. The main strategies are described in D2.5.

Here, we briefly recall the different types of tests foreseen in the WorkingAge project:

- In-lab testing: experiments are performed with a limited number of participants; they aim to do an in-depth analysis of the applicability of the method (also considering safety issues and possible interferences with other devices of the system) and, to define evaluation methodologies. In-lab testing will be carried out in task T9.2.
- In-company testing: beside single tests that will be first performed to fine-tune the different subsystems, short and long-term tests will be carried out. They aim to evaluate user acceptance, analyse the effectiveness of personalized recommendations, and possibly assess economic and social impact. In-company testing will also be used for the assessment of the ability of WA to self-improve. In company tests will be included in task T9.3 and results will be analysed in T9.4.

The present document is mainly targeted at in-company testing, while in-lab testing shall contribute to the definition of proper intervention protocols for the different pilot sites.

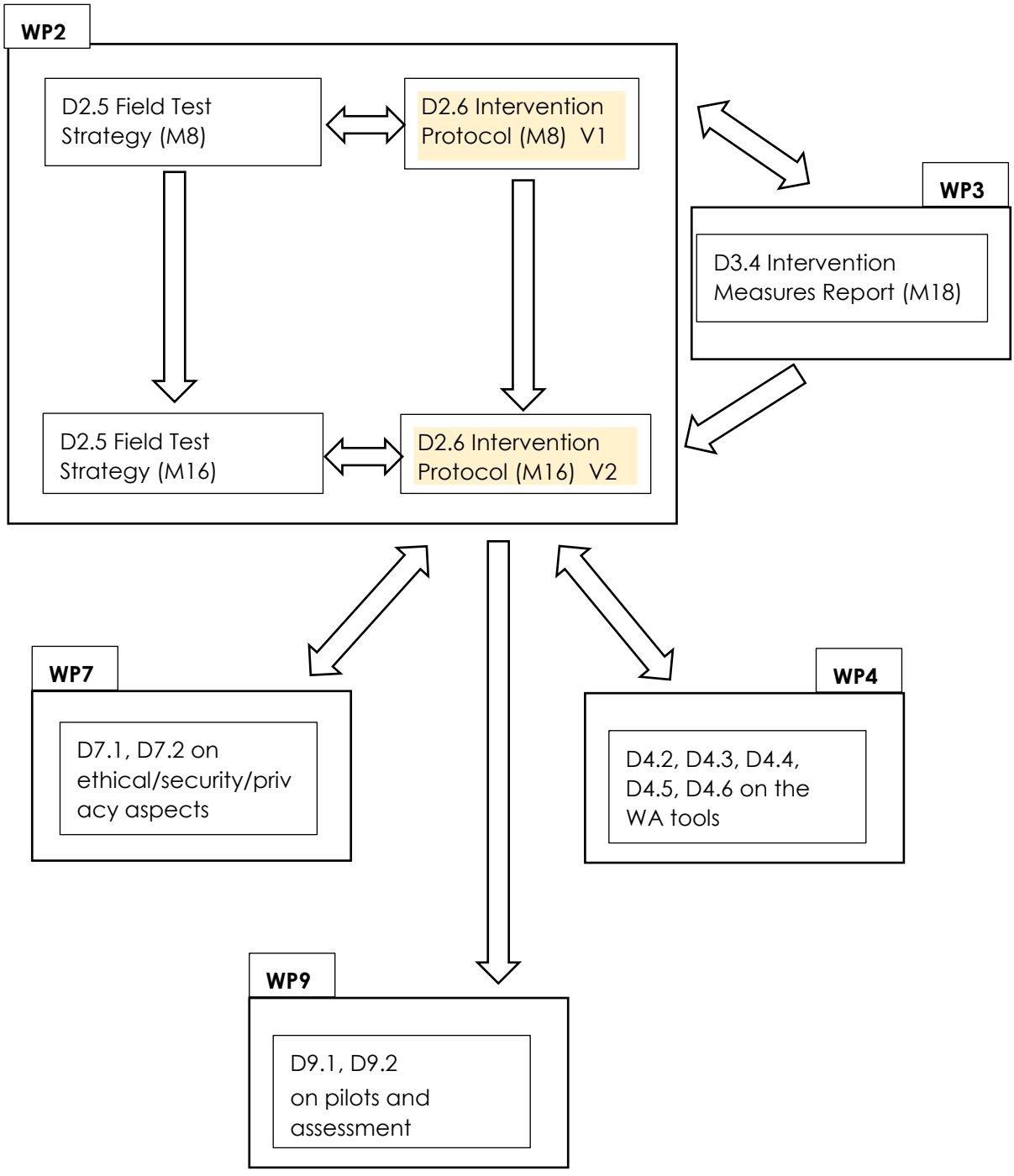


Figure 1. Relationships between D2.6 and other deliverables/work packages

2 Intervention Protocol Design

2.1 Purpose of the Pilots Tests

To test and validate an innovative HCI-based tool able to measure the emotional/cognitive/health state of people at workplace taking into account also environmental conditions.

Objectives of the pilot tests:

- To test the validity of the WA tool.
- To create awareness and prevent risks;
- To induce behavioural change on lifestyle to improve subjective wellbeing.

2.2 Research Method Overview

WorkingAge adopts HCI devices to monitor users and collect quantified and structured data; data are then analysed to evaluate possible risks of the individuals at their workplace, suggesting them different intervention measures. Interaction with the users will occur through touch/gestures/voice control interfaces, but also with traditional interfaces on smartphone/tablet etc. which will be part of the *WA Tool*.

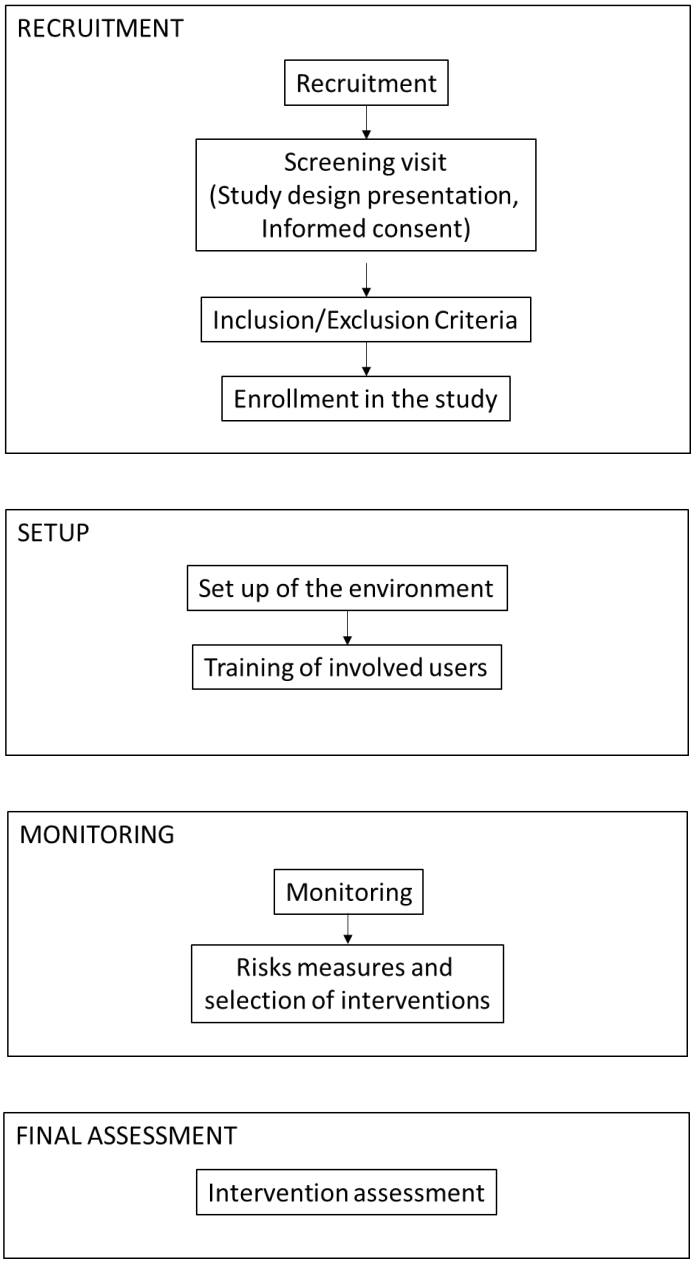
Participants will test the WA Tool at three different pilot sites, corresponding to three different scenarios: Office, Manufacturing, Driving.

The intervention protocol will be declined over the different scenarios and will include:

- The study setting and design: it describes all the phases of the pilot studies, from participants enrolment, to their monitoring and interventions procedures;
- Methods and rules about data and safety management;
- Guidelines for obtaining informed consent.

Being strictly related to the design of the pilot tests, the next section provides an overview of the main tests phases.

2.3 Overview of the Main Phases of the Pilot Tests



Recruitment. Participants will be recruited at each pilot site by the pilot site company. They will be invited to attend a screening visit with the aim of establishing eligibility. In particular, the participant will be informed about the objectives of the study, its aim and outcomes, the experimental procedures, the benefits and risks associated with the study. An informed consent will be signed at this stage, and the user profile will be identified by means of interviews/questionnaires. Inclusion/exclusion criteria are used to select the participants, according to the requirements specified in D2.5. Finally, the selected group is enrolled in the study.

Setup. The setup for the testing requires both to prepare the environment with sensors and desks/participants with devices, and to train the participants. This phase aims also to guarantee acceptability of intervention by explanation of the intervention to the participants and reduce possible anxiety due to the fact that the participant is monitored.

Monitoring. Participants will be monitored through the WA tools. The collected data will be analysed to detect possible risks of the individuals and suggesting them different intervention measures.

Final assessment. In this phase, the expected outcomes for the intervention will be measured by means of indicators/measures/KPIs. They are defined in D2.1 and D3.4. See

ùTable 1 for initial KPIs.

ASPECT		TARGET	KPI	MEASSUREMENT MODEL	RANGE	TRESHOLD	PROJECT KPI	INTERVENT WHEN LOWER
FUNCTIONAL		All	Requirements Bazaar (http://requirements-bazaar.org)	collective voting process,	NA	Simple majority	Included in system	NA
ACCEPTABILITY / USABILITY		Primary Secondary user	Effectiveness /productivity / safety /satisfaction / appreciation / usability motivation/ used	Observation, Survey; SUS ;SUMI, WA Research questions	0-5	3 (>68 SUS)	Above scope in 60% of testers	Modification in software for 2nd Research Cycle
VALIDITY		Secondary /Tertiary users	Data Comparison between measurements and diagnosis made by WA System and Medical Grade systems	Data deviation	NA	NA	Negligible deviation	sensorization hardware modification for 2nd Research Cycle Search
HCI / IoT/ HEALTH TESTING	Physical, Environmental	Primary User	Ergonomic/IoT sensors	Observation/ Data deviation	NA	NA	Negligible deviation	Change posture advise
	Psychosocial: Cognitive Emotional assessment		Psychological	Observation/ Data deviation	0 to 1	0.70	Maintained in 60% of the testers	New testers, interventions
			Emotional	ESM ITEMS PHQ and GAD score	0-25	11-19: Medium score		
	Working		Working conditions	Decent work indicators[149] Some of the indicators will be chosen to be used by the system	TBD	TBD	Above the media	Create interventions
	Health wellbeing: Quality of life and general health Activities of daily living inventory Lifestyle Assessment		Physical health, Psychological, Health Indicators, Social Interaction Indicators	WHOQOL , EQ5	1-5	3	Above scope in 60% of testers	New testers, or intervention actions
			Understanding / Learning / Usage /Attractiveness/ Acceptance	ADCS-MCI-ADL	0-5	3	Above scope in 60% of testers	
			Nutritional	Mini-Nutritional Assessment (MNA)	0-50	23.5	Controlled	
			Physical	WA games HRQOL	Un/Healthy day physical	Healthy day	70% Healthy days	
			Social	LSNS-6, AdaBoost classifier algorithms	0-30	>12	Above scope in 60%	
INTERVENTIONAL VIABILITY & COMPLIANCE	Work Parameters	Primary/ secondary users	Environment	Intervention with Stat. Tests for Effect Size Questionnaires	--	---	Improved	Include new activities, Change exercises, Add new networks
			Ergonomic					
			Psychosocial					
	Cognitive Emotional	Primary User	Improvement in executive functions	Inhibition Test, Planning Test	'effect size' 0-∞	0.25 moderate [150151]		Include new activities
			Improvement in mood	Mood scale	0-∞	0.25 moderate		
	Lifestyle		Nutritional	Intervention with Stat. Tests for Effect Size Questionnaires	--	---	Intervention followed by 60% of the testers75% of the time	Include new diets
			Physical	Measure MET	0-max	600 per week		Change exercises
			Social	Social Engagement and networking scores	NO /very active	Active		Add new networks
ADHERENCE/ SUSTAINABILITY		Primary User	Adherence/ sustainability	Reported average weekly compliance Use of the networks to report improvement attrition rate Tests for Dropout and Compliance; TAM	---	---	65% of the testers finished the tests	Modify WA
INTERVENTIONS' EFFECTIVENESS		Primary User	EVALUATION OF LONG TERM EFFECTS OF ALL INTERVENTIONAL VIABILITY & COMPLIANCE TESTS				Improved	Include more interventions.

ùTable 1 Initial KPIs (see also WP2 – T2.1)

2.4 Requirements for Protocol Design

This section reports important requirements for the design of the pilot sites protocol, in order to prepare the operational manual and perform the tests in WP9.

General, referring to the whole study

- The roles and persons involved in the protocol that will perform all the requested phases shall be identified

Recruitment phase

- The eligibility criteria shall be identified in terms of inclusion and exclusion criteria
- The informed consent shall be defined (guidelines for its definition are provided in Section 4)
- Incentives/compensations for participants shall be defined

Setup phase

- The training procedure of the participants shall be defined
- The environmental setup shall be defined
- For each device, the installation procedure, usage instructions, and possible risks (e.g., any possible side effect, allergies to materials etc.) for the participants shall be defined

Monitoring phase

- Intervention measures will be defined in D3.4
- For measures/indicators refer to D2.1 and D3.4

Assessment phase

- A data analysis plan, including all the statistical analyses shall be defined

Interventions and Ethical/Privacy issues

Since interventions involve humans, the pilots will be subject to local/regional/national *ethical* approval according to national procedures. Personal information will be anonymized as defined in D2.3 Data Management Plan. All necessary steps to ensure ethical and legal compliance, e.g. data protection and privacy issues, are addressed in T2.3 and WP7.
These aspects will be considered in Section 4, describing the guidelines for the specification of the informed consent.

Risks and mitigation measures

The protocol shall include all the activities that may reduce risks of failures during the pilot studies. This must be done in accordance with the Risk Mitigation Plan (D1.2).

Examples of risks, whose measures shall be considered in the protocol:

- Participant abandonment before tests conclusion / Insufficient users recruited for pilot tests: D2.3 details pilot strategy and rules for recruitment, motivation, inclusion and exit plans, statistical estimation of the user sample, to cope with abandon and withdraw. Dissemination activities towards users/volunteers cases will increase their motivation.
- Low degree of participant interest in the tests: Communication & dissemination plans. Test design including participant encouragement as well as rewarding schemes.

Quality Control and Protocol compliance

Responsibilities for quality control and protocol compliance are defined as follows:

- T9.2 partners are responsible for in-lab test quality;
- T9.3 partners for in-company tests quality;
- WP9 leader (Intras) coordinates and monitors the whole study protocol.

3 Intervention Protocol Template

This is a draft version of the intervention protocol template.

1 GENERAL INFORMATION

PROTOCOL TITLE: xxxx
PROTOCOL DATE: xx/xx/xxxx
REVISION DATE(s): ….

ROLES AND RESPONSIBILITIES

Pilot Site Name	[Name]
Pilot Site Coordinator	[Name, Affiliation, Address]
General Coordinator of the pilot test	[Name, Affiliation, Address]
Other investigators	[Role, Name, Affiliation]

LIST OF ABBREVIATIONS

Abbreviation	Abbreviation definition
…	….

[Compliance declaration]
This study will be conducted in compliance with the protocol, applicable regulatory requirements, and [PILOT SITE] policies and procedures.

2 INTRODUCTION

RATIONALE AND PURPOSE

[Report a brief summary of innovative solution/ new technologies/approaches that will be applied; research question that the study addresses, potential benefits]

OBJECTIVES

Primary objectives [Report primary objectives]

Secondary objectives [Report secondary objectives]

3 METHODS: PARTICIPANTS, INTERVENTIONS, OUTCOMES

STUDY SETTING

[Description of the environment in which the study will be conducted – this should take into account also local regulations]

STUDY DESIGN

POPULATION: [Number of subjects, age, etc. needed to guarantee the validity of the study]

RECRUITMENT RULES: [How participants will be recruited at the pilot site/ include also possible participants rewards]

ELIGIBILITY CRITERIA

INCLUSION CRITERIA: [List inclusion criteria]

EXCLUSION CRITERIA: [List exclusion criteria]

STUDY DURATION: [for the entire study and for subjects' participation]

STUDY PROCEDURE: [Describe the general procedure for the pilot site]

INTERVENTIONS

[List of the types of interventions that may be applied (see also D3.4) – consider also adherence of intervention requirements, i.e., deviations from the foreseen intervention]

OUTCOME MEASURES

Primary outcome measures

Secondary outcome measures

[Report psychological, physical, cognitive & social health measures from sensors, speech & other HCI interactions that will assess primary and secondary objectives – In particular: define measurement variables, methods for aggregating results, possible timelines for measurements, etc.]

PARTICIPANT TIMELINE

[Summarize time schedule for recruitment, monitoring/interventions, assessment of the typical participant]

4 DATA AND SAFETY MANAGEMENT

Retention [Rules about participants' retention/withdrawal – Definition of data that need to be recorded about the retention]

Ethics/Protection of Participants [How participants are protected from the ethical point of view]

Confidentiality [Data collection methods and rules that guarantee confidentiality of the study-related information]

Dissemination policy of results

4 Guidelines for the Informed Consent

The informed consent for the participant shall provide information to the potential subject to enroll about the following points:

- Name of the study
- Who is the principal investigator and the study sponsor?
- Has this study been evaluated by an ethical committee? Which one and when?
- What happens if I participate to the study? (Clear description of the equipment being used to perform the recordings; description should make clear any safety issues when using the devices that might occur. Report the goals of the session, explain data collection protocol, time, duration, frequency, list of activities/experiments, number of sessions, describe potential risks, if any)
- Am I obliged to participate? (define the participation as voluntarily)
- Which are my rights? (possibility to withdraw from the study)
- Which are the possible benefits due to my participation to the study? (Provide briefly what are the benefits for the participant of the study and what are the risks, if any)
- What should I do to participate?
- How is confidentiality of information guaranteed? (Type of information to be gathered - explain which sensitive information will be stored and processed and explain what are the security measures that will be taken during this procedure; provision of details about permanent storage of the data and the responsible owner for this data; A specific informative and a specific consent should be provided to the participant for collecting and storing video, audio, photographic data)
- To whom may I ask for more information? (Define contact point to refer to for questions and solution of any problems)

References

[1] Bartholomew Eldrigde, L. K., Markham, C. M., Ruiter, R. A. C., Fernàndez, M. E., Kok, G., & Parcel, G. S. (2016). Planning health promotion programs: An Intervention Mapping approach (4th ed.). Hoboken, NJ: Wiley.

[2] Bartholomew, L. K., Parcel, G. S., Kok, G., & Gottlieb, N. H. (2001). Intervention Mapping: Designing theory and evidencebased health promotion programs. Mountain View, CA: Mayfield Publishing.

[3] Green, L.W. (1974). Toward cost–benefit evaluations of health education: some concepts, methods, and examples. Health Education Monographs 2 (Suppl. 2): 34–64.