



Towards large-scale adaptation and tailored implementation of evidence-based primary cancer prevention programs in Europe and beyond (PIECES)

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1. Introduction

This deliverable described the processes and activities that were undertaken as part of the localization process of the PIECES study protocol, as described in D4.1.

2. Methods

As WP4 leader, Amsterdam UMC (AUMC) led the process of localization of the study protocol. We applied the following procedures in the process of localization of the study protocol.

- Alignment with local implementation sites
- Training local researchers
- Translation process
- Ethical procedures
- Other localization processes.

These activities are further explained in this deliverable.

2.1. Alignment with local implementation sites

As described in D4.1 we held 3 rounds of 1-on-1 meetings with all implementation sites, we organized monthly meetings, and had a joined consortium meeting. This allowed us to obtain knowledge about their local research context and incorporate their preferences into the current study protocol.

Through dissemination activities and informal discussions, the University of Limerick expressed interest in joining the PIECES project and leveraging the toolkit to implement primary cancer prevention programs in Ireland. As a result, an agreement was formalized to integrate them into the PIECES consortium, clearly defining their responsibilities and opportunities within the project. We therefore, also held 1-on-1 meetings with them in June 2024 and November 2024.

One of the key findings of these meetings that were incorporated into the current study protocol is the inclusion of level 3, yet also allowing for localization if local resources are not sufficient.

Furthermore, each implementation site will focus on different risk factors (i.e. health behaviors), different target populations, implementation settings, therefore the level 2 evaluation will vary across sites.

However, we have standardized level 1 evaluation, to address the primary objectives of the study.

2.2. Training local researchers

As described in D4.1 we organized a central training for local researchers. During the training special time was devoted to localization of the study protocol to the local context. Guidance was provided and questions were answered by AUMC/Trimbos.

2.3. Translation process

Core to the level 1 evaluation is the standardized pre-post survey aimed to capture changes in the members of the implementation team with regards to readiness, usefulness and sustainability as well as mechanisms of impact as a results of using PCP-IT.

We follow a strict procedures to translate the survey items to the local language.

All sites were provided with a translation template (see screenshot figure 1), that we explained during the central training.

A	B	C
	English	Please provide the translation for the blue text in column B3-B8
TITLE	INTRODUCTION	DUTCH
TEXT	You have been invited to participate in this survey because you will be using, or are currently working with, the Primary Cancer Prevention Implementation Toolkit (PCP-IT).	
TEXT	The purpose of this survey is to gather your opinion regarding your experiences with the PCP-IT.	
TEXT	The survey contains 13 questions and completing the survey should take approximately 15 minutes.	
TEXT	The survey can be paused and resumed at any time and your responses will be automatically saved.	
TEXT	At the end of the survey, you can share comments, ask questions, or provide any additional feedback you may have.	

INSTRUCTIONS TRANSLATIONS:

This Excel document is designed to translate the pre-post survey from English into your local language. It contains 7 sheets, each corresponding to a section of the survey (INTRODUCTION, SECTION 1 to 6). Please provide translations for the text highlighted in blue in Column B for each row.

Once complete, please return the document with your translations **by November 22nd**. For questions, please reach out to Rixt Smit (r.a.smit@amsterdamumc.nl)

Figure 1. Template for translation provided to local researchers in November 2024.



The local translation process will be conducted by 2 implementation site members. The first translator will translate the items from English to the local language. Next the second translator will conduct a back translation check. For any items that back translation provides an inconsistency, discussions between the two translators will be held. If needed a third translator will be asked for help.

After returning the completed translation file to AUMC, this will be imported into the central data management system. Before launch each implementation site will conduct a final check for inconsistencies.

With regards to interview topic lists, the planned training on qualitative research scheduled in May 2025 will address translation issues for these research instruments.

2.4. Ethical procedures

On August 7th 2024, AUMC submitted the overall ethical proposal to the Amsterdam UMC ethical board. Since the PIECES project involves non-medical implementation research, a non-WMO proposal was submitted. Non-WMO research refers to studies that fall outside the scope of the Medical Scientific Research Involving Human Subjects Act (WMO).

During the 1-on-1 meetings with the site, the consortium meetings, as well as the monthly meetings, localization of the protocol was discussed with all partners. As mentioned before level 1 evaluation is standardized. Yet, level 2 and level 3 localization is needed. At the date of writing this deliverable, the study protocol localization for these levels is still ongoing, as local implementation teams are formed to start using the PCP-IT from December onwards. Depending on the decisions made in this process, the local level 2 and level 3 evaluations might vary. We will address further localization activities in the upcoming D4.4 (interim report on study operation), and D4.5 (final report on study operation) deliverables.

To guide localization of the study protocol, and ethics, we have incorporated guidance in the research manual, and included a short version of the study protocol. Furthermore, the overall ethical proposal was made available to local implementation sites, as well as exchanging local submitted ethical proposals will be stimulated.

3. Conclusion

By co-creating and having several rounds of feedback from our implementation sites, we were able to develop a standardized protocol for level 1 evaluation, as well as provide guidance for localization of the protocol to level 2 and 3. We will address further localization activities in the upcoming D4.4 (interim report on study operation), and D4.5 (final report on study operation) deliverables.