

EVALUATION METHODOLOGY FOR PILOT CPPA ACTIONS (deliverable D3.5)

Contribution to WP3 – Design of the Pilot Programme Methodology and Tools





Authors

 ONCE University School of Physiotherapy, Autónoma University of Madrid (EUF ONCE-UAM)

With the support of:

- Irish Society of Chartered Physiotherapists (ISCP)
- Kilkenny County Council
- Europe Region of World Physiotherapy

DISCLAIMER

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 EACEA. Neither the European Union nor the granting authority can be held responsible for them.





INDEX

1.	ABBREVIATIONS AND ACRONYMS	4
2.	INTRODUCTION	5
	2.1 Introduction to the UcanACT project	
	2.2 Introduction to the Evaluation Methodology	
3.	DATA COLLECTION	7
3	3.1 Who will collect data?	7
3	3.2 How will data be collected?	7
3	3.3 When will data be collected?	8
4.	METHODOLOGY	9
2	4.1 Quantitative evaluation	9
	4.1.1 Participants Evaluation	9
	Personal data	9
	Health information	9
	Main outcomes of Pilot CPPA actions	11
	UcanACT App Evaluation	14
	Intervention Evaluation	15
2	4.2 Qualitative evaluation	16
5.	PLANNED STATISTICAL ANALYSIS	19
6.	REFERENCES	
7.	ANNEXES	25





7.1 Annex 1: Questionnaires	25
7.1.1International Physical Activity Questionnaire: Short Form (IPAQ-S	F)25
7.1.2 QLQ-C30	27
7.1.3 EUROQOL-5D-5L	29
7.1.4 Self-Rated Fall Risk Questionnaire	31
7.1.5 Brief Fatigue Inventory	32
7.1.6 System Usability Scale (SUS)	33
7.1.7 User Engagement Scale Short Form (UES-SF)	34
7.2 Annex 2: Data collection Logbooks	35
7.2.1 Round 1 of Pilot CPPA actions (pre-intervention record)	35
7.2.2 Round 2 of Pilot CPPA actions (pre-intervention record)	37
7.2.3 Round 1 and 2 of Pilot CPPA actions (post-intervention record)	39





1. Abbreviations and Acronyms

BFI Brief Fatigue Inventory

CES Citizens Engagement Strategy

CPPA Cancer-Prevention Physical Activity

EIAE Exercise-Induced Adverse Events

FRQ Fall Risk Questionnaire

GDPR General Data Protection Regulation

HEPA Health Enhancing Physical Activity

ID Identification Number

IPAQ-SF International Physical activity questionnaire - Short Form

MCID Minimal Clinically Important Difference

MOOC Massive Open Online Course

NCCN National Comprehensive Cancer Network

PA Physical Activity

PR1 Pilot Round 1

PR2 Pilot Round 2

PT Physiotherapists

PIM Practical Intervention Methodology

PUGS Public Urban Green Spaces

QoL Quality of Life

SD Standard Deviation

SH Stakeholders

SUS System Usability Scale

UES-SF User Engagement Scale Short Form

VAS Visual Analogue Scale

WHO World Health Organization





2. Introduction

2.1 Introduction to the UcanACT project

The UcanACT project - Urban ACTion for cancer prevention: adult and senior citizens practice physical activity within public urban green spaces to prevent cancer diseases - is an intersectoral initiative funded by the European Union, and joining together physiotherapists, local authorities, non-profit organisations, higher education, and research institutions from eight organisations from five EU countries. Coordinated by the Europe Region of World Physiotherapy, the UcanACT partnership all come together to engage adults and senior citizens to practice physical activity (PA) as a tool for cancer prevention within public urban green spaces (PUGS).

More specifically, the UcanACT project aims at encouraging the participation of adults and senior citizens over the age of 50 who have never suffered from cancer (primary prevention), those diagnosed with cancer (secondary prevention), or cancer survivors (tertiary prevention) in physical activity (PA) within PUGS.

2.2 Introduction to the Evaluation Methodology

To apply physical activity as a tool for cancer prevention, the project partners reviewed scientific research demonstrating the positive benefits of physical activity for cancer prevention among adults and senior citizens, with a specific focus on outdoor physical activity sessions. These research activities formed the foundation for several key project deliverables, including the Citizens Engagement Strategy (CES), the Practical Intervention Methodology (PIM), the Massive Open Online Course (MOOC) and the UcanACT App. These tools are the pillars of the implementation phase of the project, which consist of kick-off





trainings and executing Pilot cancer-preventive physical activity (CPPA) actions to test and validate the physical activity exercises, outlined in PIM, developed during the preparation phase. Three pilot territories will host the Pilot CPPA actions: Bologna (Italy), Kilkenny (Ireland) and Munich (Germany), where approximately 270 adults and senior citizens will take part.

This report specifically aims to present the evaluation strategy that will be carried out for measuring the impact of the pilot actions to be organised from 2024 within two rounds and run for about 12 weeks each. The evaluation will consist of two main parts: quantitative evaluation (participants, UcanACT App and intervention evaluation) and qualitative evaluation. The tools that will be used for this process will be scientifically validated questionnaires, functional tests and open interview questions. The main aim for this report is to explain in a sensible way each part of the evaluation and how and when it should be implemented.

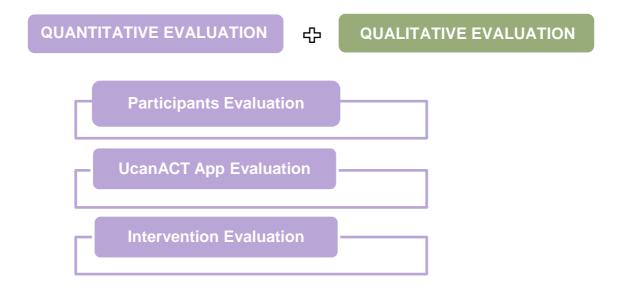


Figure 1. Evaluation structure

The authors would like to declare that this is an evaluation proposal that combines the current scientific evidence with the implementation context of this project, designed with the valuable contributions from the members of the consortium. Other proposals may be valid as well.





3. Data Collection

This section describes how data will be collected throughout the project lifetime. Details on the nature of the processing (who will be in charge of collecting data, how and when will the UcanACT project collect data, etc) will be provided and the specificities of data to be collected will be explained in subsequent sections.

3.1 Who will collect data?

The people in charge of collecting data will be the physiotherapists (PT) and other health professionals, caregivers, local stakeholders (SH) that will be involved in the project implementation activities within the three pilot territories.

3.2 How will data be collected?

Extra meetings will be organised for data collection purposes. During these events, participants will meet in an indoor location to fill out all the questionnaires with the support of PTs, SHs and members from the UcanACT team from each pilot territory. Data will be collected using the LimeSurvey platform¹ which complies with the European Union's General Data Protection Regulation (GDPR). Specific profiles for participants and professionals will be programmed into LimeSurvey, along with the questionnaires and data to be completed by each group. A version of these questionnaires, which could be filed out on the paper form, can be consulted in the annexes.

UcanACT team members from each pilot territory will be in charge of creating a user identification number (ID) for each participant. ID will be personal and unique and cannot be changed throughout the project lifetime. The first ID's digit will be a letter which will refer to the pilot territory the participant belongs to: B (Bologna), K (Kilkenny) and M (Munich). The letter will be followed by four numbers assigned according to the participant's order of arrival within the project (e.g., K0001,





K0002). In the event where there are several locations within the same pilot territory, the first number will designate each of the locations (e.g., 1. Savena district B1001).

The evaluation team, represented by ONCE, will only have access to the ID and health data collected on each participant. The identification number is required to guarantee the anonymity of data so that the person can no longer be identified directly or indirectly. Data can therefore be shared between centres and/or countries without violating the privacy regulation.

3.3 When will data be collected?

The UcanACT consortium will identify several dates for data collection, depending on the start and end dates of the two rounds of Pilot CPPA actions.

Identification and personal data, as well as some clinically relevant data for the development of the Pilot CPPA actions, will only be gathered before the first Pilot Round (PR1). If the subject did not participate in PR1, this data will be collected before the second Pilot Round (PR2). Data on quality of life, physical activity, risk of falls and fatigue will be collected before and after each of the pilot rounds. Finally, data on engagement and feedback on the Pilot intervention and on the UcanACT App will only be gathered after PR1 and PR2.





4. Methodology

4.1 Quantitative evaluation

4.1.1 Participants Evaluation

Personal data

First, for identification and anonymisation purposes, participants will be assigned an identification number. Socio-demographic data, like gender and age (in years) will be collected. In relation to gender, multiple response options have been selected with the intention of being inclusive and respectful of diversity. Thus, the participant will be able to choose between "male", "female", "non-binary", "prefer not to say" and "prefer to self-identify".

Health information

Given that the main aim of the UcanACT project is to promote physical activity as a tool for cancer prevention, it was deemed appropriate to collect certain general data on this pathology. It will contribute to enrich the subsequent statistical analysis of the data and to analyse them in the light of the information collected on cancer. The following information will be gathered:

- Whether or not participants have been diagnosed with cancer.
- If diagnosed:
 - When they were diagnosed
 - What type of cancer they were diagnosed with
 - If the participant is receiving any cancer treatment at the moment of the Pilot CPPA actions, what type it is?

These variables should be known before PR1 and PR2 and not after, as they are not expected to change during the intervention.





In addition, there are different conditions frequently associated with cancer or usually present among older adults and senior citizens that may influence participant's performance in physical activity sessions, or/and that must be taken into account for their safety. Information regarding the presence of any of these conditions will be collected prior to the start of PR1 and PR2 to include them in the data analysis.

For more detailed information, please consult section 6.2 "Key considerations for exercises with participants" of the Practical Intervention Methodology document.

Quantitative Evaluation: Health Data (Participants)									
PERIOD OF MEASUREMENT	MEASURE	TOOL							
Pre PR1 + PR2	Presence of condition: Peripheral neuropathy Lymphedema Ostomy Frailty Mobility limitation Diabetes Osteoporosis	Yes/No question. In case of bone metastasis, please indicate where: pelvis, lumbar spine, thoracic spine or ribs, proximal femur, all, other.							
	 Urinary Incontinence Bone metastases								

Table 1. Conditions Frequently Associated with Cancer/Elders

It was also considered appropriate to collect information on Exercise-Induced Adverse Events (EIAE), and the number of times they occur. Events described at the adapted National Comprehensive Cancer Network (NCCN) Triage Approach² have been considered EIAE. This data should be collected during and at the end of both pilot rounds.

For more detailed information, please consult section 5.4 "Medical clearance" of the Practical Intervention Methodology document.





Qı	articipants)		
PERIOD OF MEASUREMENT		MEASURE	TOOL
During and personal presentation of the presen	post	 Appearance and number of EIAE Peripheral neuropathy Arthritis/musculoskeletal issues Poor bone health Lymphedema Lung or abdominal surgery Ostomy Cardiopulmonary disease Ataxia Extreme fatigue Severe nutritional deficiencies Worsening/changing physical conditions Bone metastases 	Yes/No question. In case of bone metastasis, please indicate where: pelvis, lumbar spine, thoracic spine or ribs, proximal femur, all, other.

Table 2. Adapted National Comprehensive Cancer Network Triage Approach Based on Risk of Exercise-Induced Adverse Events²

Main outcomes of Pilot CPPA actions

Physical activity, Quality of Life (QoL), fatigue and risk of falls have been selected as main outcomes of the Pilot CPPA actions. They were chosen for their relevance as health indicators in cancer patients, according to the literature, and for their tendency to change with increased physical activity, as noted in previous research. The tools selected to measure these variables are further explained below.

Given that they are expected to change during the implementation of the pilot rounds, these variables will be measured before (PRE) and after (POST) both Pilot CPPA actions. For more detailed information, please consult the Practical Intervention Methodology document.





• Physical Activity: International Physical Activity Questionnaire: Short Form (IPAQ-SF)³ is a suitable instrument for the assessment of physical activity in adults between 18 and 69 years old. The IPAQ-SF consists of 7 questions about the frequency, duration and intensity of activity (moderate and intense) performed in the last seven days, as well as walking and sitting time on a working day.

The IPAQ-SF has been shown to have high reliability (ranging from 0.66 to 0.88). To see the IPAQ questionnaire, please refer to Annex 1.

Quality of Life (QoL):

EORTC QLQ-C30 (QLQ-C30)⁴ has been selected to measure QoL in participants diagnosed with cancer. It is a cancer-specific questionnaire validated in more than 80 languages. It is composed of 30 questions or items that assess the QoL in relation to physical, emotional and social aspects and the general level of functionality of patients diagnosed with cancer. This questionnaire assesses the QoL of the week prior to the time of filling it in. Selected from other options for its goodness of fit and predictive performance.⁵

The reliability coefficients for the multi-item scales ranged from 0.54 to 0.86 before treatment and from 0.52 to 0.89 Cronbach's alpha coefficient during treatment. With one exception, reliability estimates were similar across the three cultural subgroups. All interscale correlations were statistically significant (P<.01).6 To see the EORTC QLQ-C30 questionnaire, please refer to Annex 1.

The 5 level EuroQol-5D version (EQ-5D-5L)⁷ has been selected to measure QoL in participants not diagnosed with cancer. It is a standardised instrument developed to describe and assess quality of life in relation with health for the general population. The EQ-5D-5L instrument consists of 2 parts: the EQ-5D-5L descriptive system and the Visual Analogue Scale (VAS).





- The EQ-5D-5L descriptive system comprises 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.
- With the VAS, the subject scores his health between two extremes, 0 and 100, worst and best health status imaginable.

The EQ-5D-5L is a reliable and valid generic instrument.⁸ To see the EQ-5D-5L questionnaire, please refer to Annex 1.

- Risk of falls: Self-rated fall risk questionnaire (FRQ)^{9,10} is a 12-item questionnaire designed to screen older adults who are at risk of falling. It is validated in different languages and is widely used. FRQ is composed of 12 questions specific to the individual's physical functional performance and different fall risk factors. Each question can be scored as 0 or 1/2, depending on the question, and the total possible score is 14. A higher score indicates a higher risk of falling. If the patient scores 4 points or more, he/she is considered to be at risk of falling. The FRQ has excellent self-perceived internal consistency (Cronbach's alpha 0.936). To see the FRQ questionnaire, please refer to Annex 1.
- <u>Fatigue</u>: Brief Fatigue Inventory (BFI)^{11,12,13} is validated in multiple languages (English, Spanish, Italian and German) and is used to quickly assess the severity and impact of cancer-related fatigue and its interference with daily life. It consists of 9 items on a scale from 0 to 10: three items evaluate the severity of fatigue while the six remaining evaluate the way in which fatigue has interfered with different aspects of life (general activity, mood, ability to walk, normal work, relationships with other people and fun capacity). The BFI has good internal consistency (Cronbach's Alpha of 0.96) which supports its reliability. To see the BFI questionnaire in more detail, please refer to Annex 1.





Main Outcomes (Participants)								
PERIOD OF MEASUREMENT	MEASURE	TOOL						
Pre and Post PR1 + PR2	Physical Activity	IPAQ-SF ³ (7 Items)						
Pre and Post PR1 + PR2	Quality of Life	QLQ-C30 ⁴ (in participants diagnosed with cancer, 30 items) EQ-5D-5L ⁷ (in participants not diagnosed with cancer, 25 items)						
Pre and Post PR1 + PR2	Fatigue	FRQ ^{9,10} (12 items)						
Pre and Post PR1 + PR2	Risk of falls	BFI ¹¹⁻¹³ (9 Items)						

Table 3. Main Outcomes Variables

UcanACT App Evaluation

For the quantitative evaluation of the UcanACT App, two measurement scales will be used: the System Usability Scale (SUS)¹⁴ and the User Engagement Scale Short Form (UES-SF)¹⁵. SUS consists of 10 items with a Likert scale to answer each of them, whereas UES-SF is composed of 12 items with also a Likert scale to answer them. Both scales have been used in a variety of digital domains. Please note that when we talk about "usability" or "user engagement" we are referring to:

- Usability: the ability of any individual to carry out the action specified in the App without any type of complication, and the possibility of fulfilling the objective pursued.
- User Engagement: measures how much users are actively participating in a product or service. It encompasses a range of behaviours, such as commenting, sharing, liking, and returning to the product or service over time.





These two scales will be used after the end of PR1 and PR2. Participants, PTs and SHs who were involved in both Pilot rounds and used the UcanACT App will be asked to fill them out.

App Quantitative Evaluation (Participants + professionals)							
PERIOD OF MEASUREMENT	MEASURE	TOOL					
Post PR1 + PR2	Usability	System Usability Scale (SUS) ¹⁴ (10 Items)					
Post PR1 + PR2	Engagement to the App	User Engagement Scale Short Form (UES-SF) ¹⁵ (12 Items)					

 Table 4: UcanACT App quantitative evaluation

Intervention Evaluation

In this section, "intervention" is understood as the Practical Intervention Methodology of the UcanACT project, which includes all its elements as a whole and understood as a unit (namely the MOOC, the UcanACT App, and Pilot CPPA actions). To quantitatively evaluate the intervention, it was decided to use two variables: effectiveness and engagement.

Effectiveness is understood as the capacity of the intervention to generate change in the level of physical activity, quality of life, fatigue and risk of falls among participants. These values have already been described in the section "Participant Evaluation".

Engagement is a very complex psychological construct consisting of different dimensions, such as behavioural, cognitive and affective (for more detailed information, please consult the section 5 of the Citizens Engagement Strategy document). Part of the assessment of this variable will therefore be approached from a qualitative point of view (see below). The quantitative perspective will be approached by monitoring various aspects of the subjects' participation in the Pilot CPPA actions. For more detailed information, please refer to table 5.





Interv	Intervention Quantitative Evaluation (Participants)								
PERIOD OF MEASUREMENT	MEASURE	TOOL							
Pre PR1 + PR2	Number of participants	Number							
Post PR1 + PR2	Engagement: Session attendance (number of sessions the participant didn't attend the PA sessions).	Attendance records (number and reasons of non-attendance)							
Post PR1 + PR2	Engagement: Dropouts (number of participants that abandoned PA sessions).	Number and reasons why							
Post PR1 + PR2	Engagement (cognitive): Goals	Single-Item/ Modified Borg Scale e.g. I understand the goals of the CPPA sessions/App This intervention will help me reach my goals							

Table 5. Intervention Quantitative Evaluation

4.2 Qualitative evaluation

In terms of qualitative evaluation, a series of questions will be asked to participants and professionals involved in the Pilot CPPA actions. They will gather feedback about their experience within the intervention as a whole, namely on the CPPA actions, the MOOC and the UcanACT App. Different dimensions will be explored: general opinion, appropriateness, feasibility, expectations compliance, goals achieved and App usability. These questions will be completed after the first and second Pilot Round.

The questions will be asked through semi-structured interviews (focus groups). The table 6 shows the list of questions that will be asked. They have been





selected after a literature review of qualitative analysis of prior health interventions. 16,17,18

Intervention	Qualitative Evaluation (Pa	articipants + Professionals)
PERIOD OF MEASUREMENT	MEASURE	TOOL
Post PR1 + PR2	General opinion	 Are you satisfied with the results of this intervention? Why are you satisfied/dissatisfied with this intervention? Would you recommend this intervention to someone else who needs it? What limitations have you detected in yourself or in the intervention that have hindered your participation?
Post PR1 + PR2	Expectations compliance	Has this intervention met your expectations? Why?
Post PR1 + PR2	Goals achievement	 Do you consider that you have achieved the goals that you set for yourself when you started this intervention? Can you explain the reasons why?
Post PR1 + PR2	Appropriateness of the intervention	 Do you consider this intervention is well conceived as regards the objective sought? If you had the opportunity to make changes or improvements, would you change any aspect of this intervention?
Post PR1 + PR2	Feasibility of the intervention	Do you think this intervention was easy to carry out?





		•	What factors do you think make its implementation more difficult/easier?
Post PR1 + PR2	App usability	•	Do you think the UcanACT App is user friendly? Why? Would you change any of its functionalities? Which ones and why?

Table 6. Intervention Quantitative Evaluation





5. Planned statistical analysis

As part of the evaluation, it will be necessary to do a statistical analysis of the data collected to fully understand the impact of the UcanACT project. Here is a brief description of the steps that we plan to carry out for this purpose:

- 1. Description of the sample (of each group separately, and of the whole sample) using mean + standard deviation (SD) or median deviation + quartiles for quantitative variables, and absolute and relative frequencies for qualitative variables. Descriptive graphs such as bar and/or sectional graphs for discrete quantitative and qualitative variables and histograms for continuous quantitative variables will also be made.
- 2. The homogeneity of the different groups of participants will be analysed by comparing the descriptors of the variables and statistical tests.
- 3. Normality will be tested by means of graphical tests (histograms or quartile Q-Q plots). To see pre-post variation, the student's t-test will be used for related samples under the assumption of normality, and the nonparametric Wilcoxon signed-rank test for paired samples when normality cannot be assumed. The results will be presented as the difference (pre vs. post) in mean, or with the median difference in case of the nonparametric test, and their corresponding 95% confidence intervals.
- 4. In addition to evaluating the pre-post difference, it would be useful to evaluate what percentage of patients achieved a clinically important improvement or "Minimal Clinically Important Difference" (MCID). MCID will be obtained from the published literature for the main outcomes of the intervention (physical activity, quality of life, risk of falls and fatigue). In the variables MCID cannot be found in the literature, partners will establish it





based on their own clinical experience with findings in bibliography that supports their decision.

- 5. We also propose to perform multivariate linear regression models to analyse pre-post intragroup differences adjusted for covariates such as sex or age. Since baseline physical activity is controlled in the inclusion criteria, it would no longer be necessary to adjust for it in this part.
- 6. Likewise, it could be interesting to consider multivariate logistic models to study factors associated with improvement. That is, to evaluate whether men or women are more likely to improve on any given scale or whether age is associated with improvement, for example.
- 7. The analysis of variables that are only taken post pilot, will be carried out by mean + standard deviation (SD) or median deviation + quartiles for quantitative variables, and absolute and relative frequencies for qualitative variables. Descriptive graphs such as bar and/or sectional graphs for discrete quantitative and qualitative variables and histograms for continuous quantitative variables will also be made.





6. References

- LimeSurvey Free online survey tool [Internet]. Limesurvey.org. [Cited October 26th, 2023]. Available at: https://www.limesurvey.org/
- Campbell KL, Winters-Stone KM, Wiskemann J, May AM, Schwartz AL, Courneya KS, et al. Exercise guidelines for cancer survivors: Consensus statement from international multidisciplinary Roundtable. Med Sci Sports Exerc [Internet]. 2019;51(11):2375–90. Disponible at: http://dx.doi.org/10.1249/MSS.0000000000002116
- 3) Lee PH, Macfarlane DJ, Lam TH, Stewart SM. Validity of the international physical activity questionnaire short form (IPAQ-SF): A systematic review. Int J Behav Nutr Phys Act [Internet]. 2011;8(1). Available at: http://dx.doi.org/10.1186/1479-5868-8-115
- 4) Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, et al. The European organization for research and treatment of cancer QLQ-C30: A quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst [Internet]. 1993;85(5):365–76. Available at: http://dx.doi.org/10.1093/jnci/85.5.365
- 5) Ameri H, Yousefi M, Yaseri M, Nahvijou A, Arab M, Akbari Sari A. Mapping EORTC-QLQ-C30 and QLQ-CR29 onto EQ-5D-5L in colorectal cancer patients. J Gastrointest Cancer [Internet]. 2020;51(1):196–203. Available at: http://dx.doi.org/10.1007/s12029-019-00229-6
- 6) Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, et al. The European organization for research and treatment of cancer QLQ-C30: A quality-of-life instrument for use in international clinical trials





in oncology. J Natl Cancer Inst [Internet]. 1993;85(5):365–76. Available at: http://dx.doi.org/10.1093/jnci/85.5.365

- 7) Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res [Internet]. 2011;20(10):1727–36. Available at: http://dx.doi.org/10.1007/s11136-011-9903-x
- 8) Feng YS, Kohlmann T, Janssen MF, Buchholz I. Psychometric properties of the EQ-5D-5L: a systematic review of the literature. Qual Life Res [Internet]. 2021;30(3):647–73. Available at: http://dx.doi.org/10.1007/s11136-020-02688-y
- 9) Kitcharanant N, Vanitcharoenkul E, Unnanuntana A. Validity and reliability of the self-rated fall risk questionnaire in older adults with osteoporosis. BMC Musculoskelet Disord [Internet]. 2020;21(1). Available at: http://dx.doi.org/10.1186/s12891-020-03788-z
- 10) Caldara C, Dell'Aquila R, Pacchiani S, Maestrini S, Pellegrini R, Casati M, et al. L'autovalutazione del rischio di caduta: Validazione italiana del Fall Risk Questionnaire [FRQ]. [Self-assessment of fall risk: Italian validation of the Fall Risk Questionnaire [FRQ]]. L'infermiere [Internet]. 2019; 56(1): e1–e9. Italian. Available at: https://www.infermiereonline.org/2019/04/17/lautovalutazione-del-rischio-di-caduta-validazione-italiana-del-fall-risk-questionnaire-frq/
- 11) Mendoza TR, Wang XS, Cleeland CS, Morrissey M, Johnson BA, Wendt JK, et al. The rapid assessment of fatigue severity in cancer patients: Use of the brief fatigue inventory. Cancer [Internet]. 1999;85(5):1186–96. Available at: <a href="http://dx.doi.org/10.1002/(sici)1097-0142(19990301)85:5<1186::aid-cncr24>3.0.co;2-n">http://dx.doi.org/10.1002/(sici)1097-0142(19990301)85:5<1186::aid-cncr24>3.0.co;2-n





- 12) Catania G, Bell C, Ottonelli S, Marchetti M, Bryce J, Grossi A, et al. Cancer-related fatigue in Italian cancer patients: validation of the Italian version of the Brief Fatigue Inventory (BFI). Support Care Cancer [Internet]. 2013;21(2):413–9. Available at: http://dx.doi.org/10.1007/s00520-012-1539-z
- 13) Radbruch L, Sabatowski R, Elsner F, Everts J, Mendoza T, Cleeland C. Validation of the German version of the brief fatigue inventory. J Pain Symptom Manage [Internet]. 2003;25(5):449–58. Available at: http://dx.doi.org/10.1016/s0885-3924(03)00073-3
- 14) Peres SC, Pham T, Phillips R. Validation of the System Usability Scale (SUS): SUS in the wild. Proc Hum Factors Ergon Soc Annu Meet [Internet]. 2013;57(1):192–6. Available at: http://dx.doi.org/10.1177/1541931213571043
- 15) O'Brien HL, Cairns P, Hall M. A practical approach to measuring user engagement with the refined user engagement scale (UES) and new UES short form. Int J Hum Comput Stud [Internet]. 2018; 112:28–39. Available at: http://dx.doi.org/10.1016/j.ijhcs.2018.01.004
- 16) O'Cathain A, Goode J, Drabble SJ, Thomas KJ, Rudolph A, Hewison J. Getting added value from using qualitative research with randomized controlled trials: a qualitative interview study. Trials [Internet]. 2014;15(1). Available at: http://dx.doi.org/10.1186/1745-6215-15-215
- 17) Manetti S, Vainieri M, Guidotti E, Zuccarino S, Ferré F, Morelli MS, et al. Research protocol for the validation of a new portable technology for real-time continuous monitoring of Early Warning Score (EWS) in hospital practice and for an early-stage multistakeholder assessment. BMJ Open [Internet]. 2020;10(12): e040738. Available at: http://dx.doi.org/10.1136/bmjopen-2020-040738





18) Carrigan A, Austin EE, Clay-Williams R, Hibbert PD, Maka K, Holden N, et al. Birang Daruganora: a protocol for a qualitative study to elicit Aboriginal and Torres Strait Islander community views about cultural needs and experiences for a new Australian health facility. BMJ Open [Internet]. 2023;13(4): e069951. Available at: http://dx.doi.org/10.1136/bmjopen-2022-069951





7. Annexes

7.1 Annex 1: Questionnaires

7.1.1 International Physical Activity Questionnaire: Short Form (IPAQ-SF)3

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the Iast 7 days. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1.	During the last 7 days , on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling?
	days per week
	No vigorous physical activities Skip to question 3
2.	How much time did you usually spend doing vigorous physical activities on one of those days?
	hours per day
	minutes per day
	Don't know/Not sure
activit some	about all the moderate activities that you did in the last 7 days . Moderate ies refer to activities that take moderate physical effort and make you breathe what harder than normal. Think only about those physical activities that you did least 10 minutes at a time.
3.	During the last 7 days , on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.
	days per week
	No moderate physical activities → Skip to question 5
SHORT	LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised August 2002.

Co-funded by the European Union



4.	How much time did you usually spend doing moderate physical activities on one of those days?
	hours per day
	minutes per day
	Don't know/Not sure
home	about the time you spent walking in the last 7 days . This includes at work and at walking to travel from place to place, and any other walking that you have done for recreation, sport, exercise, or leisure.
5.	During the last 7 days , on how many days did you walk for at least 10 minutes at a time?
	days per week
	No walking → Skip to question 7
6.	How much time did you usually spend walking on one of those days?
	hours per day
	minutes per day
	Don't know/Not sure
days. time.	ast question is about the time you spent sitting on weekdays during the last 7 . Include time spent at work, at home, while doing course work and during leisure. This may include time spent sitting at a desk, visiting friends, reading, or sitting or down to watch television.
7.	During the last 7 days, how much time did you spend sitting on a week day?
	hours per day
	minutes per day
	Don't know/Not sure
This	is the end of the questionnaire, thank you for participating.
SHORT	LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised August 2002.





7.1.2 QLQ-C30⁴



EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:		L	_	_					
Your birthdate (Day, Month, Year):		L	1		_	1	_	_	
Today's date (Day, Month, Year):	31	L	1	_	_	1	_	_	

		Not at All	A Little	Quite a Bit	Very Much
1.	Do you have any trouble doing stremuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.	Do you have any trouble taking a <u>long</u> walk?	1	2	3	4
3.	Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4
Du	ring the past week:	Not at All	A Little	Quite a Bit	Very Much
6.	Were you limited in doing either your work or other daily activities?	1	2	3	4
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8.	Were you short of breath?	1	2	3	4
9.	Have you had pain?	1	2	3	4
10.	Did you need to rest?	1	2	3	4
11.	Have you had trouble sleeping?	1	2	3	4
12.	Have you felt weak?	1	2	3	4
13.	Have you lacked appetite?	1	2	3	4
14.	Have you felt nauseated?	1	2	3	4
15.	Have you vomited?	1	2	3	4
16.	Have you been constipated?	1	2	3	4

Please go on to the next page





During the past week:	Not at All	A Little	Quite a Bit	Very Much				
17. Have you had diarrhea?	1	2	3	4				
18. Were you tired?	1	2	3	4				
19. Did pain interfere with your daily activities?	1	2	3	4				
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4				
21. Did you feel tense?	1	2	3	4				
22. Did you worry?	1	2	3	4				
23. Did you feel irritable?	1	2	3	4				
24. Did you feel depressed?	1	2	3	4				
25. Have you had difficulty remembering things?	1	2	3	4				
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4				
Has your physical condition or medical treatment interfered with your <u>social</u> activities? 1 2 3								
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4				
For the following questions please circle the numb best applies to you	ber bet	ween]	and	7 that				
29. How would you rate your overall <u>health</u> during the past week?								
1 2 3 4 5 6	7							
Very poor Ex	Very poor Excellent							
30. How would you rate your overall quality of life during the past week?								
1 2 3 4 5 6	7							

Very poor



Excellent

[©] Copyright 1995 EORTC Quality of Life Group. All rights reserved. Version 3.0



7.1.3 EUROQOL-5D-5L7

Under each heading, please tick the ONE box that best describes your health TODAY. MOBILITY I have no problems in walking about I have slight problems in walking about I have moderate problems in walking about I have severe problems in walking about I am unable to walk about SELF-CARE I have no problems washing or dressing myself I have slight problems washing or dressing myself I have moderate problems washing or dressing myself I have severe problems washing or dressing myself I am unable to wash or dress myself USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities) I have no problems doing my usual activities I have slight problems doing my usual activities I have moderate problems doing my usual activities I have severe problems doing my usual activities I am unable to do my usual activities PAIN / DISCOMFORT I have no pain or discomfort I have slight pain or discomfort I have moderate pain or discomfort I have severe pain or discomfort I have extreme pain or discomfort ANXIETY / DEPRESSION I am not anxious or depressed I am slightly anxious or depressed I am moderately anxious or depressed I am severely anxious or depressed I am extremely anxious or depressed

2

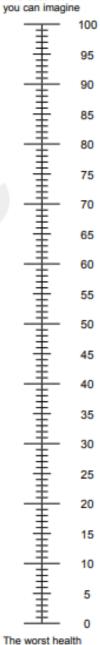
UK (English) © 2009 EuroQol Group EQ-5D™ is a trade mark of the EuroQol Group





- . We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
 0 means the <u>worst</u> health you can imagine.
- . Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =



The best health

The worst health you can imagine

3

UK (English) © 2009 EuroQol Group EQ-5D™ is a trade mark of the EuroQol Group





7.1.4 Self-Rated Fall Risk Questionnaire^{9,10}

- 1. I have fallen in the last 6 months. No_Yes_ (2 points)
- 2. I am worried about falling. No_Yes_ (1 point)
- 3. Sometimes, I feel unsteady when I am walking. No_Yes_ (1 point)
- I steady myself by holding onto furniture when walking at home. No_Yes_
 (1 point)
- I use or have been advised to use a cane or walker to get around safely.
 No_Yes_ (2 points)
- 6. I need to push with my hands to stand up from a chair. No_Yes_ (1 point)
- 7. I have some trouble stepping up onto a curb. No_Yes_ (1 point)
- 8. I often have to rush to the toilet. No_Yes_ (1 point)
- 9. I have lost some feeling in my feet. No_Yes_ (1 point)
- 10. I take medicine that sometimes makes me feel light-headed or more tired than usual. No_Yes_ (1 point)
- 11. I take medicine to help me sleep or improve my mood. No_Yes_ (1 point)
- 12. I often feel sad or depressed. No_Yes_ (1 point)

Result: __ (4 or more points-risk of falls).





7.1.5 Brief Fatigue Inventory¹¹⁻¹³

			В	rief F	atigu	e Inv	ento	ry	HOSP	ITAL#
Date:	/_	/	_						ī	ime:
Kirinis	Last				Firs	t		Middle	Initial	-
	hout our ou felt ur									ired or fatigued. No
	se rate y best des						ss) by	circlin	g the	one number
0) 1 No Fatigue	2	3	4	5	6	7	8	9	10 As bad as you can imagi
										one number tha
best	describ	es you	USU	AL lev	el of fa	tigue	during	past 2	24 hou	urs.
	0 1 No Fatigue	2	3	4	5	6	7	8	,	9 10 As bad as you can imag
	se rate y describ									one number tha urs.
	0 1 No Fatigue	2	3	4	5	6	7	8	9	9 10 As bad as you can imag
	e the on igue has					how, d	luring	the pa	st 24	hours,
A.	General				_		_		_	
	1	2	3	4	5				9	10
0 Does not in	nterfere					6	7	8	3	Completely Interfer
B . 0	Mood 1	2	3	4	5	6	7	8	9	Completely Interfer
B. 0 Does not in	Mood 1 nterfere			4	_		_	_	_	Completely Interfe
B. 0 Does not in	Mood 1 hterfere Walking 1			4	_		_	_	_	Completely Interfer
B. 0 Does not in C. 0 Does not in	Mood 1 hterfere Walking 1 hterfere	ability 2 work (i	3	4	5	6	7 7 de the	8	9	10 Completely Interfe 10 Completely Interfe 10 Completely Interfe daily chores)
B. 0 Does not in C. 0 Does not in	Mood 1 nterfere Walking 1 nterfere Normal 1	ability 2	3	4	5	6	7	8	9	10 Completely Interfe
B. 0 Does not in C. 0 Does not in D. 0 Does not in	Mood 1 nterfere Walking 1 nterfere Normal 1	ability 2 work (i	3 nclud	4 les bot 4	5 5 th work 5	6 6 c outsi	7 7 de the	8 8 home	9 9 and (10 Completely Interfe 10 Completely Interfe 10 Completely Interfe daily chores) 10
B. 0 Does not in C. 0 Does not in D. 0 Does not in E. 0 Does not in	Mood 1 herfere Walking 1 herfere Normal 1 herfere Relation 1 herfere	work (i 2 ns with	3 nclud 3 other	4 les bot 4	5 5 th work 5	6 6 k outsi	7 7 de the	8 8 home 8	9 9 and 6	10 Completely Interfe 10 Completely Interfe 20 Completely Interfe daily chores) 10 Completely Interfe
B. 0 Does not in C. 0 Does not in D. 0 Does not in E. 0 Does not in	Mood 1 hterfere Walking 1 hterfere Normal 1 hterfere Relation 1 hterfere Enjoym	work (i 2 ns with	3 nclud 3 other	4 les bot 4	5 5 th work 5	6 6 k outsi	7 7 de the	8 8 home 8	9 9 and 6	Completely Interfer 10 Completely Interfer 10 Completely Interfer daily chores) 10 Completely Interfer





7.1.6 System Usability Scale (SUS)¹⁴

All questions should be answered with the Likert scale below.

- 1. I think that I would like to use the App frequently.
- 2. I found the App unnecessarily complex.
- 3. I thought the App was easy to use.
- 4. I think that I would need the support of a technical person to be able to use this App.
- 5. I found the various functions in this App were well integrated.
- 6. I thought there was too much inconsistency in this App.
- 7. I would imagine that most people would learn to use this App very quickly.
- 8. I found the App very cumbersome to use.
- 9. I felt very confident using the App.
- 10. I needed to learn a lot of things before I could get going with this App.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1	2	3	4	5





7.1.7 User Engagement Scale Short Form (UES-SF)¹⁵

All questions should be answered with the Likert scale below.

- FA-S.1 I lost myself in this experience.
- FA-S.2 The time I spent using the UcanACT App just slipped away.
- FA-S.3 I was absorbed in this experience.
- PU-S.1 I felt frustrated while using the UcanACT App.
- PU-S.2 I found the UcanACT App confusing to use.
- PU-S.3 Using the UcanACT App was taxing.
- AE-S.1 The UcanACT App was attractive.
- AE-S.2 The UcanACT App was aesthetically appealing.
- AE-S.3 The UcanACT App appealed to my senses.
- RW-S.1 Using the UcanACT App was worthwhile.
- RW-S.2 My experience was rewarding.
- RW-S.3 I felt interested in this experience.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1	2	3	4	5





7.2 Annex 2: Data collection Logbooks

7.2.1 Round 1 of Pilot CPPA actions (pre-intervention record)

ID Nu	mber:		Date:	
Perso	nal Da	ata		
0	Birth	date (day/month/year):/_	/	
0	Gend	er (please mark one option): Male:		
	0	Male:		
	0	Female:		
	0	Non binary:		
	0	Prefer not to say:		
	0	Prefer to self-identify:		
Healtl	h Infor	rmation		
0	Have	you been diagnosed with car	ncer? Yes: No:	
0	If yes	, please answer:		
	0	When were you diagnosed?	? (day/month/year)	//
	0	What type of cancer were y	ou diagnosed with	?
	0	Are you currently receiving	any cancer treatme	ent? Yes: No:
	0	If yes, please indicate wh	ich one (chemoth	erapy, radiotherapy,
		hormone therapy, other):		
0	Pleas	e mark if you have any of the	e following:	
		Conditions	Yes	No



Peripheral neuropathy



Lymphedema						
Ostomy						
Frailty						
Mobility limitation						
Diabetes						
Osteoporosis						
Urinary Incontinence						
Bone metastases						
In case of bone metastasis please indicate where:						
Pelvic: Lumbar: Thoracic/ribs: _	Proximal femur:					
Other: All:						

Questionnaires

- **Self-Rated Fall Risk Questionnaire:** ____ (4 or more points indicates risk of falls).
- International Physical Activity Questionnaire (please mark the result):

Results	Final
Inactive	
Minimally active	
НЕРА	

•	QLQ 30:
•	EuroQol 5D-5L:
•	Brief Fatique Inventory:





7.2.2 Round 2 of Pilot CPPA actions (pre-intervention record)

ID Nui	mber:		Date:
Perso	nal Da	nta*	
0	Birth o	date (day/month/year)://	-
0	Gend	er (please mark one option):	
	0	Male:	
	0	Female:	
	0	Female: Non binary: Prefer not to say:	
	0	Prefer not to say:	
	0	Prefer to self-identify:	
Healtl	n Infor	mation*	
0	Have	you been diagnosed with cancer?	Yes: No:
0	If yes,	please answer:	
	0	When were you diagnosed? (day	//month/year)://
	0	What type of cancer were you dia	agnosed with?
	0	Are you currently receiving any c	ancer treatment? Yes: No:
	0	If yes, please indicate which o	ne (chemotherapy, radiotherapy,
		hormone therapy, other):	
(*) This	data wil	I only be taken if you have not participated	I in PR1.

Conditions	Yes	No
Peripheral neuropathy		
Lymphedema		
Ostomy		

o Please mark if you have any of the following conditions:





Frailty					
Mobility limitation					
Diabetes					
Osteoporosis					
Urinary Incontinence					
Bone metastases					
In case of bone metastasis please indicate where:					
Pelvic: Lumbar: Thoracic/ribs: _	Proximal femur:				
Other: All:					

Questionnaires

- Self-Rated Fall Risk Questionnaire: ____ (4 or more points indicates risk of falls).
- International Physical Activity Questionnaire (please mark the result):

Results	Final
Inactive	
Minimally active	
HEPA	

•	QLQ	30:	
---	-----	-----	--

- EuroQol 5D- 5L: _____
- Brief Fatigue Inventory: ______





7.2.3 Round 1 and 2 of Pilot CPPA actions (post-intervention record)

ID Nu	mber: Date:			
Atten	Attendance record (to be filled out by the professional)			
0	Please register the number of sessions the patient was not able to attend:			
0	Please register, if possible, the reasons for not-attendance:			
0	Did the patient drop out of the project? Yes: No:			
0	Please register, if possible, the reasons why the patient dropped out of the project:			
Additional data				
0	Have you used the UcanACT App during the CPPA actions? Yes: No:			





Exercise Induced Adverse Events

Please mark with a cross in the corresponding box if some of these events happened during sessions:

EIAE	Mark	Number of times that happened
Peripheral neuropathy		
Arthritis/musculoskeletal issues		
Poor bone health		
Lymphedema		
Lung or abdominal surgery		
Ostomy		
Cardiopulmonary disease		
Ataxia		
Extreme Fatigue		
Severe nutritional deficiencies		
Worsening / changing physical conditions		
Bone metastases		
In case of bone metastasis please indicate where: Pelvic: Lumbar: Thoracic/ribs: Proximal femur: Other: All:		

Questionnaires

- Self-Rated Fall Risk Questionnaire: ____ (4 or more points indicates risk of falls).
- International Physical Activity Questionnaire (please mark the result):





Results	Final
Inactive	
Minimally active	
НЕРА	

•	QLQ 30:
•	EuroQol 5D-5L:
•	Brief Fatigue Inventory:
•	System Usability Scale (SUS):
•	User Engagement Scale Short Form (UES-SF):





Qualitative Evaluation

1- How would you describe your satisfaction with the project?
2- What aspects of this project most affect your satisfaction?
3- If you had the opportunity to make changes or improvements, would you
change any aspect of the project?
4- How do you think this project could help you in the future?
5- Can you describe how you would recommend this protocol to someone
else who needed it?
6- What bothers you the most about using this protocol?

