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A MIXED-METHOD STUDY PROTOCOL FOR ENGAGING FAMILY CAREGIVERS IN MEANINGFUL ACTIONS FOR SUCCESSFUL AGEING IN PLACE

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PLACE4CARERS:**A MIXED-METHOD STUDY PROTOCOL FOR ENGAGING FAMILY CAREGIVERS IN
MEANINGFUL ACTIONS FOR SUCCESSFUL AGEING IN PLACE**

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Abstract

Introduction. Engaging family caregivers in the care network could be a critical asset to make the “ageing-in-place” imperative a reality. This is particularly evident in remote and rural areas, where family caregivers can fill the gaps that exist due to the fragmentation of the social and welfare system. However there is little knowledge about family caregivers of elderly citizens expectations towards health and care services and scarce attentions has been devoted to their perspectives particularly in rural and remote areas. Place4Carers (P4C) project aims to co-design an innovative, context-based, organizational model of social and care services for family caregivers of elderly citizens living in the mountain area of Vallecamonica (Italy). This innovative service model should be a way to guarantee ageing-in-place processes.

Methods and analysis. Place4Carers is a community-based participatory research project that features 7 work packages. WP1 consisted of an extensive survey on unmet of the population of family caregivers receiving services in Vallecamonica. WP2 consisted of a scoping literature review on existing interventions to engage family caregivers living in remote areas. Additional focus groups were aimed to co-generate ideas for shaping caregiver oriented services and organizational models. WP3 will be aimed to co-create new ideas about the objectives, features and characteristics of a new service able to address the caregiver needs and expectations emerged in the previous modules of the research. WP4 is dedicated to the testing of the service ideas co-created in WP3 through a piloting intervention. Finally, WP5 will assess the transferability of the intervention to other similar contexts.

Ethics and dissemination. The study has been approved by the Ethics Committees of the Department of Psychology of Università Cattolica del Sacro Cuore (Milan) and Politecnico of Milan. Results will be disseminated through peer reviewed journals, scientific meetings and direct presentation to the general population.

Keywords: Caregiver engagement; Community Based Participatory Research; service co-creation; ageing-in-place

Strengths and limitation of this study

- ▶ This study aims to ideate, co-plan and implement a new - better accessible and sustainable - service targeted to family caregivers of elderly citizens on the basis of the participative cooperation among family caregivers, elderly citizens, researchers and welfare system representatives.
- ▶ This study will represent the first research to enhance and sustain the role of family caregivers in making the ageing in place a sustainable reality in remote and rural areas;
- ▶ It uses a Community Based Participatory Research approach to engage all the actors involved in the care of elderlies
- ▶ It is a multi-stakeholder, multi-level and self-sustained project, which will have both short-term and long-term beneficial effects
- ▶ The study is conducted in a specific territory and the results should be tested in other contexts to enhance their validity.

INTRODUCTION

Rationale of the study

This study's rationale is based on the insight that successful ageing is today a complex phenomenon that is strictly intertwined with the "places" and spaces that people belong to [1]. According to this vision, "space" is not static or a simple 'background' to events, but is very much a part of social relationship [2]. Moreover, spaces are not only physical but also have social, psychological and symbolic meanings. People may have quite different lived experiences, expectations and opinions related to a particular space. None of these aspects of space (social, physical and symbolic) is necessarily more 'real' or important than any other. Instead, they are interconnected and directly dependent on each other [3]. In covering these key points that shape the rationale of this study, in the next paragraph, a more detailed description of the theoretical lenses adopted in this project is provided.

Ageing: the need for a multidimensional and multidirectional approach

Ageing is a dynamic process that lasts a lifetime, determined by internal factors such as genes, and external factors such as the physical, social and cultural spaces [4]. In past decades, the secret of longevity was primarily attributed to genetic factors, however today researchers have found that environmental factors – also in terms of life spaces - have an increasingly relevant weight in prolonging human life and, above all, the quality of life of the elderly [5,6].

By assuming a social-ecological framework of analysis [9] the Place4Carers project (P4C) will disentangle the role of spaces and of their interrelated dynamics in the ageing process. Particularly we will refer to the concept of spaces in the ageing process assuming a three-fold perspective:

1. *Ageing space as exosystem: the uniqueness of ageing in remote rural areas.* In the Italian context – similarly to other European countries - the elderly are becoming a prominent feature of the population, especially in more remote and rural areas which currently experience health inequities including limited access to health and social services [10]. Literature suggests that inequities in health access for elderly rural population are more frequent if compared with their urban counterparts, [11]. The ageing population presents a range of challenges for the health and aged care system, particularly in the remote rural areas where the workforce shortage and the lack of access to specialist services are confounding factors. It is interesting to note that "ageing in rural areas has received less attention in the literature than the proportions of older people living in rural areas might suggest" [12]. Given that much of the research on the ageing population to date has been subjected to "urban-related" bias, it is time to begin considering data on the ageing process when occurring in rural/remote areas.

Many authors have noted that the specific needs of rural and remote areas in term of health and social-related services have not been met by service provision derived from criteria from urban contexts [11,13,14]. This research focusing on older persons living on the margins, both geographically and socially, have argued that in both policy and economic debates the local experiences of older people living in rural communities have been often ignored [15]. Further research efforts are needed to fill this gap into the literature.

2. *Ageing space as mesosystem: opportunity and challenges of the "ageing-in-place" imperative.* "Ageing-in-place" is a popular term in current aging policy and is today recognized as a strategic priority for making the ageing process more sustainable for both individuals and societies. "Ageing in place" is defined as "remaining living in the community, with some level of independence, rather than in residential care" [16]. Claims that people prefer to age in place abound [1] because it is seen as enabling older people to maintain independence, autonomy, and meaningful relations in terms of connection to social support, including friends and family [17]. Having people remain in their homes and communities for as long as possible also avoids the costly option of institutional care and is therefore favored by policy makers, health providers, and by many older people themselves. The term "place" has several dimensions that are interrelated: a physical dimension that can be seen and touched like home or neighborhood, a social dimension involving relationships with people and the

ways in which individuals remain connected to others, an emotional and psychological dimension, which has to do with a sense of belonging and attachment, and a cultural dimension, which has to do with older people's values, beliefs, ethnicity, and symbolic meanings... Livable communities should offer affordable and appropriate services that a continuum of care to effectively engage elderly and their family in effective and sustainable health and social care.

Several interventions and projects both at a national and international level are today devoted to reducing the fragmentation of welfare services by putting the citizen – and his/her needs - at the centre of service delivery. However, a study conducted in Europe [19] found that a fragmented system of services was unable to meet the holistic needs of ageing societies, because integration between services is complex, including problems in inter-disciplinary teamwork, financing, and legal aspects. However, fragmentation and the need for integration between health and social services is on the agenda of many ageing countries [20]. Furthermore, in rural and remote context, welfare and social system often result fragmented and poorly accessible, this making even more difficult the ageing place paradigm, or at least risking transforming it in a necessity rather than in a choice and by abandoning elderly peoples and their family to directly deal with all the challenges implied in the ageing process.

3. Ageing space as microsystem: the role of family relationship and caregiving for elderly citizens. Even if the “ageing in place” approach to elderly care is promising and might have positive impact on the elderly health and social wellbeing, it might present huge challenges to families, and society as a whole, not least because many of these societies are highly family-based in respect of support for older people [16,21]. Quite simply, that family is shrinking dramatically and the role of the family is changing likewise [22]. According to the statistics, it is also a fact that informal caregivers do a significant amount of work, and research has shown that such caring places a significant burden on caregivers. Across the OECD, more than one in ten adults (family and friends) is involved in informal, typically unpaid, caregiving, defined as providing help with personal care or basic activities of daily living (ADL) to people with functional limitations [23]. The percentage of the population reporting to be informal carers across OECD countries for which data are available ranges from 8% to just over 16%. There is no clear geographic distribution in the rate of caregiving: certain southern European countries have among the highest percentages (Italy, Spain). Family caregiver engagement is indeed regarded as a key factor to improve the quality and the sustainability of care services for the elderly [25–27]. Several studies have shown that caregivers are the invisible backbone of the social and health care settings, as they facilitate the integration especially in those areas and communities with limited access to services. Despite their unquestionable role in increasing the chance of ageing-in-place for the elderly people they take care of, the caregivers experience several criticalities. In fact, caregivers attest a critical decrease on their quality of life [28], and they report health issues, such as tiredness, insomnia, depression, weight loss or gain, drug use and need for psychological support; these issues are frequently reported by women, especially if older. The European Commission report on “The indirect cost of long term care” (2013) [29] reveals that these situation of psycho-social distress is diffused also for caregivers in countries other than Italy. This is especially the case for caregivers of elderly people [29] and for those who are required to dedicate a significant amount of time and intensity of care [30]. Actually, the caregivers of elderly people often become the primary interlocutors for the health and social care services to take decisions over the patients' therapies and long-term treatments [31].

Moreover, caregivers support the compliance to treatments and therapies and they support the elderly in managing follow-ups and clinical exams [32]. Last, caregivers are often the primary sources of psychological support and empathy for the care receiver and he/she represents the social entity referral. Against this background, research shows that family caregivers who are more engaged in the care journey of their loved one have more capability to deal with stressful situations such as caregiving and thus, have less anxiety and depression and better perceived health [33–36]. By feeling more empowered and engaged in the caregiving tasks, caregivers might also reach a better work-family balance.

Appropriate engagement and tailored support of caregivers have the potential to improve their experiences and quality of life and facilitate shared decision making while enhancing the quality of care provided to older people and reducing the use of unnecessary health and social services [37], as well as increasing the effectiveness of health and social care interventions [38]. Furthermore, supporting the role of informal carers

(family and friends providing mostly unpaid care to frail seniors) is important to provide an adequate continuum of care between informal and formal care.

Figure 1 describes the threefold social-ecological framework of analysis adopted by P4C.

[please, insert figure 1 around here]

Aims

The project aims to achieve the following objectives:

1. to explore, understand and measure the needs of education, welfare, assistance and social inclusion of caregivers of elderly citizens in general and in relation to the offer of services planned by the local home care agency in the territory of Vallecamonica;
2. to assess the cost (both economic and social) sustained by families when caring for their elderly relatives and to understand the critical aspects faced when accessing and using welfare services that are present in the territory;
3. to ideate, co-plan and implement a new - better accessible and sustainable - service targeted to family caregivers of elderly citizens on the basis of the participative cooperation among family caregivers, elderly citizens, researchers and welfare system representatives;
4. to test the transferability of the new service concept into other and similar remote rural territories of the Lombardy Region (Italy).

METHODS AND ANALYSIS

Methodological approach

The proposed study is designed according to a Community Based Participatory Research (CBPR) approach [39,40], in order to engage all the relevant stakeholders and to capture the different perspectives of the actors involved in the care of elderlies and welfare services. Thanks to its participatory nature, the P4C project will be not only the occasion to deepen the aging and caregiving dynamics in the specific outreach territory of Vallecamonica. It will also be a situated co-production lab, where to engage elderly citizens, their caregivers and the welfare system to generate ideas for better accessible, effective and economically sustainable welfare services targeted to family caregivers.

This approach has the value to be grounded in the needs, issues, concerns, and strategies of communities and the community-based organizations that serve them and support and/or enhancing the strategic action that leads to community transformation and social change by directly engaging target stakeholders and stakeholders' knowledge in the research process and its outcomes. This is a partnership approach to research that equitably involves community members, organizational representatives, and researchers in all the phases of the research process. In this approach, all partners contribute expertise and ownership to reach shared decisions and to make the knowledge produced best rooted in the community experience and more able to be translated into the practice of services development.

In this project, we will mainly focus on the community of Vallecamonica in order to deepen the unique experiences and needs of family caregivers caring for elderly citizens located in that geographic area. Moreover, the involvement of the local home care agency will be a key asset in this project, in order to produce knowledge well integrated with situated interventions and policies and thus better able to generate social change and to improve the health and quality of life of community members. Community members, professionals belonging to home care agency and the researchers will collaborate in all the phases of the project in order to improve its sustainability and its ability to set the ground not only for a better knowledge production process, but also for the translation of such knowledge into a real opportunity of policy, organizational and social change. Furthermore, extra local or regional expertise will be included in the project if this will result

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3 as needed in order to improve the applicability and the depth of insight gained. We will also guarantee the
4 continuous methodological and scientific supervision of an International Advisory Board in order to validate
5 the research design and the tools used in the research. An important aspect of this study is to provide insight
6 from all the stakeholders' perspective by involving them in all the phase of the research process.
7
8
9

10 **Setting of the study**

11 The research setting is Vallecamonica that an outreach territory in Italy and local partner is ATSP the agency
12 that provide home services to local community.
13
14

15 Vallecamonica is a mountainous territory in the northern part of the Lombardy Region. It is divided into 44
16 municipalities, all of which have been categorized as "peripheral" or "ultra-peripheral", due to a poor access
17 to services, scarce infrastructures, limited economic prosperity and negative demographic trends. Residential
18 areas in Vallecamonica are geographically dispersed, and the viability is not made easy by the conformation
19 of the territory and the limited network of infrastructures and public transportation services. The population
20 living in the area is characterized by an ageing index, computed as the ratio between the number of people
21 aged 65 or more and those aged 14 or less, equal to 157,3 (the average for the Lombardy Region is 152,6;
22 DGR X/5208). The high proportion of elderly people attests a situation of diffused frailty, with several social
23 and health care needs. Against this widespread need, most of the municipalities are distant 20 to 40 km (or
24 more) from the main hospital and health care structures (DGR X/5208). Unsurprisingly, the amount of social
25 and assistance services required and provided to support the difficult access to services increases year after
26 year.
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31 **Study Design**

32 The Place4Carer Research Protocol is articulated in 5 work packages (WPs), as described in the next
33 paragraphs.
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36 ***WPI – Quantitative survey to define family caregivers needs, current services usage and sustained costs***

37 *Objectives.* This research module is conceived as an extensive assessment on the entire population of family
38 caregivers of elderly people receiving services from the ATSP in Vallecamonica aimed to:
39

- 40 • Analyze, quantify and map experiences, unmet needs, preferences and expectations of support and
41 assistance of family caregivers involved in elderly care, in general and in relation to the specific
42 service offered by ATSP;
- 43 • Perform a service and costs analysis in order to map the actual use of available services by
44 caregivers and the direct costs sustained by families for the elderly care and support;
- 45 • Identify the main target of caregiver (i.e. the more needing ones) to which address the new service
46 and to be involved in the following participatory phases of the project.
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48

49 *Tools and methods.* A quantitative survey will be designed comprehending measures of caregivers' needs,
50 levels of engagement and questions to gather information about the direct costs sustained by the families for
51 providing assistance to the elderly (i.e. out of pocket payments both for the services received by the ATSP and
52 for additional assistance services). The survey will be administered by a psychologist at caregivers' house.
53
54

55 *Sampling.* Only family caregivers that have concrete difficulties in the daily care of their dear ones will be
56 involved in the survey. Thus, we will focus on local service providers that offer long-term household services
57 for elders. Selecting criteria will be: family caregivers, whose elders have been living at home for a medium
58 to long time period assisted by two home care services that expressly will consent the interview.
59
60

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3 *Data Analysis.* Survey data will be anonymized, stored in an electronic database and shared with the other
4 partners. The data collected in the survey will be analyzed in the aim of to take a snapshot of the population
5 of the family caregivers in the area, in terms of needs, economic burden and services required.
6
7

9 ***WP2 – Narrative analysis of the literature to map existing initiatives and services for caregiver engagement***

10 *Objective.* The aim of this module will be identifying good practices described in the literature related to
11 supporting and engaging family caregivers of elderly people in rural/remote settings.
12

13 *Tools and Methods.* Scoping review approach, set out by Arksey and O'Malley (2005)[47] will be preferred
14 rather than literature review as we want to explore the conceptualization of ageing and of intervention
15 mechanisms adopted to promote caregiver's engagement which oriented such interventions. The following
16 research string will be adopted: [(caregivers OR family member*) AND (ageing OR elderly* OR old*) OR
17 (patient*) AND (support OR intervention OR program OR education OR counselling) AND (rural* OR
18 mountain* OR "hard to reach"*)]. The terms caregivers and family members will be adopted in order to
19 differentiate from professional, paid caregivers. The terms patient or older people will be included to indicate
20 the care receiver. Moreover, we will include the terms support, intervention, program, education, counselling,
21 in order to map a broader variety of initiatives. Finally, as our primary interest is on hard to reach areas, we
22 will include the terms rural, mountain and hard to reach.
23
24

25 This scoping review will be carried throughout the following scientific databases: Scopus, Psych-Info, Cinhal,
26 Pubmed.
27
28

29
30
31 *Data Analysis.* All articles will be merged in a unique database in order to remove duplicates. Secondly, titles
32 and abstracts will be checked for the inclusion criteria, and in cases of ambiguity, also full texts will be read
33 in order to be sure for the inclusion. Moreover, the reference list will be screened in order to identify additional
34 material. To be included, articles should be published from 2012, recognized European Year of Active Aging,
35 in English, and the full text must be accessible. Moreover, articles must focus on interventions during the
36 planning, piloting, implementation or analysis of the results. As a consequence, all articles that reflect on the
37 necessity to provide intervention to caregivers, without providing a service, are not included. Receivers of
38 these interventions must be informal caregivers of family members. The care receivers, as mentioned before,
39 should be over 60 years old. Finally, the geographical context of the provided service must be a hard to reach
40 area, including rural or mountain area. Articles will be analyzed at two levels. (1) Intervention characteristics:
41 objective of the intervention, characteristics of the receiver (by type of patient), context of intervention,
42 presence or absence of technologies, individual or group setting, tools and duration of the intervention. More
43 precisely, the retrieved studies will be organized according to their main objective (i.e. psychosocial
44 interventions, educational interventions, organizational interventions.) following the categorization of Roter et
45 al (1998)[48]. (2) Study characteristics: country, study design (randomized controlled trial "RCT", controlled
46 trial "CT", cross-sectional "CS", pilot "P"), sample and number of participants, outcome measures and results.
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51 ***WP3 – Co-creation workshop with caregivers***

52
53 *Objectives.* This work package of the protocol will be dedicated to co-create (together with family caregivers,
54 service providers and researchers) new ideas about the objectives, features and characteristics of a new service
55 able to address the caregiver needs and expectations emerged in the previous modules of the research.
56

57 *Tools and methods.* Focus group technique is selected as it reaches our objectives of identifying caregiver
58 needs and to co-create services for helping caregivers in their mental and physical health and in their tasks of
59 taking care of their beloved. Given the little knowledge of habits and service preferences of family caregivers
60 living in rural context and the complexity of the social problem, we will opt for integrating and deepening
surveys' quantitative data with a traditional form of focus group"[49,50] Each focus group meeting will last

about 2 hours and will be conducted by two researchers specifically trained in qualitative research. The focus group meetings will be audio recorded. To include different point of view and enrich the discussion, the focus groups will involve both users (family caregivers) and service providers (ATSP), while researchers will have the role of coordinators and moderators. With the focus group, we want to recreate a situation similar of the ordinary process of opinions creation, allowing all participants to express with a peer discussion, thanks to the presence of a trained mediator. All focus groups will develop the discussion following these phases:

- Mutual acquaintance: presentation of the project, presentation of participants with their biographical info, and description of their role as informal caregiver;
- Focus on the needs: What are the difficulties of caregiving in the context of Valle Camonica, for them and for their elders;
- Insights, ideas for the new service : starting from emerged needs, what are the caregiver ideas for a new service, with a particular attention on information, educational and psycho-social help;
- Conclusions: Caregivers, together with the moderator and members of the team of research, try to merge ideas for the new service in a unique project idea and to define it accurately.

Sampling. Caregivers included in the first stage of the research that have given their availability will be invited to be involved also in focus groups. Given the numbers expected we will try to include all caregivers that wish to participate, knowing that logistic difficulties will lead us to some abandonment. We will follow a snow-ball sampling, to arrive to an average of 8-10 participants for each focus group.

Data Analysis. All focus groups will be transcribed and analyzed using content analysis [50, 51] with a deductive approach [52]. The content analysis will analyze conversations between caregivers, grouping together recurrent instances using a pre-existing coding frame [53]. To ensure the validity and replicability of the study, we will analyze and code data according to an accurate study design. Leveraging from the systemizing literature review's results (WP 2), we will create a theoretical framework based on the needs and ideas that arise from the psychosocial, educational, organizational interventions. This framework will be detailed in categories and constructed codes that support us in labelling the focus groups' transcript [54]. The codes that emerge from the literature may be changed or integrated during the coding process. We prefer to use a deductive approach since we would like to build up the existing theory with new findings [55]. To ensure the reliability of the analysis, two researchers will code the transcripts in parallel, analyzing and checking any inconsistency. Each of the two researcher will group and order codes in the pre-defined categories of the literature framework. In case codes do not fit with any of these categories, they will create new categories as long as the content is relevant and supported by data [56]. One the set of categories is well established by the two researchers, we will discuss results and assemble the final set of categories in high-level themes that represent the main concepts of investigation. Resulting themes and categories will be compared in term of similarities and differences with the ones that arise from the literature framework [57]. To deepen our understanding of the findings, we will investigate the relationships between themes and categories. If other authors agree on the reliability of the coding process, we will try to conceptualize and generalize results [58].

WP4 - First implementation, piloting and preliminary assessment

Objectives. This WP is dedicated to the testing of the service ideas co-created in WP3 through a piloting action organized and delivered by ATSP. Specifically, the pilot study is aimed at:

- Assessing the feasibility and conditions for implementing the service in terms of effort and resources;
- Piloting the service;
- Evaluating the service.

Tools and methods. To check the consequences of services' ideas and to ensure the iterative improvement of the pilot, we will use a service prototyping approach [59]. Among the several prototyping techniques, we

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2
3 choose “The Service Prototyping Practical Framework” that guides researchers in service prototyping process
4 through six steps. First, the research team will have to state clearly the purpose of the service. Second, the team
5 should define the most suitable and effective way to use the resources and skills for the service’s
6 implementation [60]. To achieve this aim, we will perform a feasibility study for defining the capabilities and
7 resources needed under legal, economic, operational, technical and scheduling point of view [61]. Third, the
8 research team should choose the most suitable technique for implementing the service, in line with team and
9 users’ knowledge and competences. Fourth, the team should define the drivers that evaluate the service
10 resolution and quality. We will assess the pilot through a set of quantitative metrics suggested by the existing
11 literature. For each activity of the pilot, we will identify the most appropriate set of indicators. Since the number
12 of participants in this rural and remote area might not be very significant, we will integrate this quantitative
13 data with interviews. Mixing both quantitative and qualitative data in a single study will allow us to improve
14 the understanding of future issues related to the implementation of the pilot [62]. We will collect the opinion
15 of the providers of the pilot with individual interviews. Fifth, the project team will have to verify the validity
16 of the service prototyping leveraging on the results of the pilot’s assessment. Finally, the project team should
17 check the service’s satisfaction, collecting the opinion of family caregiver with one focus group at the end of
18 the pilot [60].
19
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21
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23 *Sample.* All the caregivers, whose elders are using at least one of the two type of homecare services identified
24 in the WP1, will be invited to participate to the pilot. We will spread the project’s activities and meetings
25 through both online and offline channels, to include all caregivers that wish to participate. ATSP will be in
26 charge of the pilot delivery.
27

28 *Data Analysis.* Once we will have collect the assessment’s results and the users’ opinions on the service, we
29 will try to generalize results proposing a set of barriers and enablers that may have limited or facilitated the
30 implementation of the pilot. We will start listing all possible barriers and enablers that will arise from the
31 analysis of the pilot. Then, we will compare them in term of differences, similarities, frequency of occurrence
32 and consistency. Finally, we will discuss the final list with the Research Team and other stakeholders involved
33 in the project in order to check the reliability of results.
34
35

36 ***WP5 - Assessment transferability to other regions and stakeholder involvement***

37 *Objectives.* The transferability analysis, intends to make the insights and the idea of the new service better
38 exportable to other similar extra-urban contexts. The transferability will be assessed in Valtellina, which is an
39 area geographically close to Vallecamonica and shares the same demographic challenges and similar
40 difficulties in the access to assistance and services with the specific aim to:
41

- 42 • Investigate if the needs expressed by the family caregivers in mountainous and outreach communities
43 are similar;
- 44 • Assess the transferability of the service ideas generated in WP 3;
- 45 • Engage stakeholders in the transferability, by adapting the service idea to the new specific context.
46

47
48 *Tools and methods.* The module will adopt a mixed methods design by using a qualitative study to integrate
49 and deepen the previous quantitative one. In the first study, we will distribute to the people in charge of social
50 and welfare services of local districts in Valtellina an exploratory survey for collecting their personal opinions
51 and interests in the project. The survey’s aim is twofold. First, it would like to check the interests of the local
52 districts in the project by investigating the correspondence between family caregivers’ needs. Second, it intends
53 to understand the future issues that may arise in adopting the project in the new context. Since we do not expect
54 significant number of respondents, we will integrate survey’s results by organizing focus groups with the
55 providers of long-term household in the districts that express their interest in the study. The aim of this second
56 qualitative study is to collect further insights about possible issues and barriers related to the transferability of
57 the project in that area. Based on surveys and focus groups’ results, we will organize a feasibility study that
58 will analyze legal, economic, operational, technical and scheduling constraints [63].
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3 *Sample.* At the beginning, we will present the pilot’s activities and results to the professionals in charge of
4 social and welfare services of local districts in Valtellina, collecting their interests in the project. We will
5 involve and contact the districts interested in the project to discuss a possible transferability of the service in
6 their territory. For each district that gives its availability, we will organize a focus group inviting the operators
7 and staff that are managing and providing long-term household services for elders. The direct involvement and
8 interaction with professionals and operators that might have to create the service will allow us to collect
9 insights for adopting the service in the new context.
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13 *Data Analysis.* Data from surveys and focus group will be triangulated with official and internal documentation
14 related to the welfare systems in Valtellina [64]. Results of the assessment of transferability will be verified
15 thanks interviews with key actors of the local districts of Valtellina for collecting their opinions and checking
16 the reliability of results.
17
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19 20 **PATIENT AND PUBLIC INVOLVEMENT**

21
22 Citizens and members of the public institutions will be involved in P4C at various stages of the study. We will
23 hold information/ discussion sessions with key community stakeholders (caregivers, elderly citizens, public
24 institutions) to co-create the envisaged family caregiver services and recommendations across the spectrum of
25 the project. This will help to create a positive and receptive environment for the ultimate implementation of
26 the outputs of the project. The involvement in the research Protocol of representatives belonging to both
27 private and public institutions will allow to create synergic exchange between stakeholders having different
28 points of view and resulting in alignment and cohesion of approach, without compromising independence of
29 any party. In particular, the involvement of ATSP of Vallecamonica in the project will guarantee not only the
30 access to the field and a more “ecological” insight on the ageing and caring dynamics in this territory. It will
31 also guarantee the more concrete applicability of the ideas of services developed with the real commitment of
32 the key welfare actors in the territory.
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35 This inclusion of patients/public in this way helps with enhanced recruitment and enables these participants to
36 share their experiences of taking part with others and to underline the importance of the study to people like
37 themselves. Finally, citizens and public representatives will be actively involved in disseminating the results
38 of the research.
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41 42 **PROJECT IMPLICATIONS AND FUTURE POLICY**

43
44 The P4C mission is to enhance and sustain the role of family caregiver in making the “ageing in place”
45 imperative a sustainable reality in remote and rural areas. The results of the project will contribute to deliver
46 more value to elderly citizens and health and social system, while making the welfare processes more efficient.
47 Furthermore, by enhancing the skills and the psychological wellbeing of family caregivers of elderly citizens,
48 the project will also contribute to improve quality of life and social inclusion of the elderly loved ones. Existing
49 knowledge on meaningful family caregiver engagement will be aligned, and sustainably implemented through
50 involvement of relevant stakeholders. The P4C project will deliver a transformative network structure and
51 instruments by creating the resources for making the current welfare system more responsive to the needs of
52 elderly citizens and of their family caregivers. To serve this mission, the research is a multi-stakeholder, multi-
53 level and self-sustained project, which will have both short-term and long-term beneficial effects, as outlined
54 below. Furthermore, by the implementation of the sustainability strategy the long-term impact is that family
55 caregiver engagement will be a common standard in the welfare ecosystem guided by commonly accepted
56 practices. Moreover, the P4C protocol is expected to sensitize family caregiver about the available resources
57 to be activated in the territory and how to make the healthcare/welfare process more fluid and less fragmented.
58 This would also reduce the waste of health and social resources.
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3 Overall, all the stakeholders involved in the project may benefit from each other's expertise and develop a
4 better understanding of how diverse viewpoints can positively drive and impact on successful ageing processes.
5 The impact of this is mutual trust and understanding nurtured by both the P4C results and the participation in
6 the project. The study might have also some limitation. The impact of Place4Carers activities should be
7 conceivable as local. However, since it includes actions and strategies in order to assess the generalizability of
8 the insights produced to other extra-urban contexts in Lombardy we are going to have some insights about
9 results' exportability.
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13 **ETHICS AND DISSEMINATION**

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15 The study was approved by the Ethics Committees of both Università Cattolica del Sacro Cuore and
16 Politecnico di Milano. Informed consent will be collected from all participants. Data will be treated in
17 anonymized form and only the P4C research team will have access to the data.
18

19 The research team will provide a wide dissemination of the key achievements and recommendations to diverse
20 stakeholders through various activities, thus supporting the impact of the project outcomes. Moreover,
21 caregivers will be central to dissemination of the baseline information, which helped to motivate community
22 involvement during and beyond the study.
23

24 According to these premises, the aims of the dissemination activities will be: (1) to generate awareness about
25 the concept and the main aims of the project; (2) to ensure strategic and extensive outreach to the ageing
26 research community at large and engage with all other external relevant initiatives and projects to ensure
27 optimal synergies and cross-fertilization and avoid duplication of efforts; (3) to identify opportunities to
28 collaborate in developing a cohesive and coherent ecosystem to support possible next phases of the project, its
29 adoption and its sustainability.
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34 **Contributors** GG is the study principal investigator and contributed to develop the study design and to write
35 the protocol. SB, NM, CM, EG, MC, VG, CF, RF contributed to develop the study design and to write the
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37

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40

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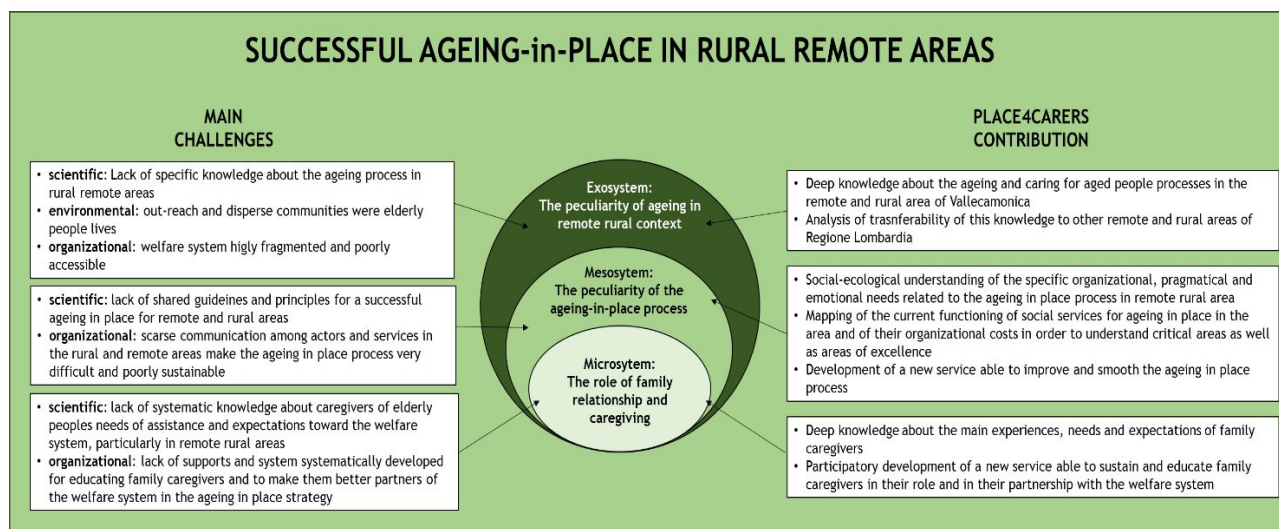
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Figure 1. A three-fold perspective on successful “ageing-in-place” processes



BMJ Open

PLACE4CARERS: A MIXED-METHOD STUDY PROTOCOL FOR ENG AGEING FAMILY CAREGIVERS IN MEANINGFUL ACTIONS FOR SUCCESSFUL AGEING IN PLACE

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PLACE4CARERS:

**A MIXED-METHOD STUDY PROTOCOL FOR ENG AGEING FAMILY CAREGIVERS IN
MEANINGFUL ACTIONS FOR SUCCESSFUL AGEING IN PLACE**

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10 **Abstract**
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13 **Introduction.** Engaging family caregivers could be a critical asset to make the “ageing-in-place” imperative
14 a reality. This is particularly evident in rural and remote areas, where caregivers can fill the gaps that exist due
15 to the fragmentation of the welfare system. However, there is little knowledge about the expectations that
16 family-caregivers have towards healthcare services in rural and remote areas.

17 Place4Carers (P4C) project aims to co-produce an innovative organizational model of social and healthcare
18 services for family caregivers of elderly citizens living in Vallecamonica (Italy). The project is expected to
19 facilitate ageing-in-place for elderly citizens helping caregivers in their daily care activities.

20 **Methods and analysis.** Place4Carers is a community-based participatory research project that features 5 work
21 packages. WP1 consisted of a survey of unmet needs of caregivers and elderlies receiving services in
22 Vallecamonica. WP2 consisted of a scoping literature review to map services that provide interventions of
23 support to caregivers living in rural and remote areas and promote engagement. WP3 organizes co-creation
24 workshops with caregivers to co-design, co-manage and co-assess ideas and proposals for shaping caregivers’
25 oriented services and organizational models. WP3 enriches the results of WP1 (survey) and WP2 (scoping
26 literature review) and aims to co-create new ideas for intervention support with and for caregivers in relation
27 to the objectives, features and characteristics of a new service able to address the caregiver needs and
28 expectations. WP4 tests the service ideas co-created in WP3 through piloting an intervention based on ideas
29 co-created with caregivers. Finally, WP5 assesses the transferability of the intervention to other similar
30 contexts.

31 **Ethics and dissemination.** The study has been approved by the Ethics Committees of the Department of
32 Psychology of Università Cattolica del Sacro Cuore and Politecnico of Milan. Results will be disseminated
33 through peer reviewed journals, scientific meetings and meetings with the general population.

34 **Keywords:** Caregiver engagement; Community based participatory research; service co-creation; ageing-in-
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Strengths and limitation of this study

- ▶ This study aims to use participatory methods to co-design an accessible and sustainable service for family caregivers of elderly citizens. Participation in the planning, design and implementation of the service will include family caregivers, elderly citizens, researchers and representatives from the welfare system (as ATSP, the agency that provide home services to local community).
- ▶ To our knowledge this is the first co-produced study that uses participatory methods to enhance and sustain the role of family caregivers to make 'ageing in place' a sustainable reality in rural and remote areas.
- ▶ This study is a multi-stakeholder, multi-level and self-sustainable project, which will have both short-term and long-term beneficial effects on the possibility to continue the service deployment even after the end of the project
- ▶ The study is conducted in a specific setting and we recommend that the results should be deployed in other contexts to enhance their validity.
- ▶ The study provides a social-ecological framework, analysing the uniqueness of ageing in rural and remote areas, opportunities and challenges of the ageing-in-place imperative, and the role of family relationship and caregiving for elderly citizens (Figure 1)

INTRODUCTION

Rationale of the study

This study's rationale is based on the insight that successful ageing is a complex phenomenon that is intrinsically intertwined with the 'places' and spaces that people belong to [1]. Spaces are not only a physical backdrop to events, but also have social, psychological and symbolic meanings[2]. People may have quite different lived experiences, expectations and opinions related to a particular space. None of these aspects of space (social, physical and symbolic) is necessarily more 'real' or important than any other. Instead, they are interconnected and directly dependent on each other [3]. Ageing is a dynamic process that is largely influenced by physical, social and cultural spaces [4]. Literature [5–8] discusses the concept of space in the ageing process from a three-fold perspective of (i) ageing spaces as eco systems, (ii) ageing spaces as meso-systems and (iii) ageing spaces as micro-systems. These inter-relationships are particularly noticeable in rural and remote areas. The research setting is Vallecamonica, an outreach territory in Italy and local partner is ATSP the agency that provide home services to local community.

Vallecamonica is a mountainous territory in the northern part of the Lombardy Region. It is divided into 44 municipalities, all of which have been categorized as "peripheral" or "ultra-peripheral", due to a poor access to services, scarce infrastructures, limited economic prosperity and negative demographic trends. Residential areas in Vallecamonica are geographically dispersed, and the viability is not made easy by the configuration of the territory and the limited network of infrastructures and public transportation services. The population living in the area is characterized by an ageing index, computed as the ratio between the number of people aged 65 or more and those aged 14 or less, equal to 157,3 (the average for the Lombardy Region is 152,6; DGR X/5208). The high proportion of elderly people attests a situation of a multidimension frailty, with several social and health care needs. Against this widespread need, most of the municipalities are distant 20 to 40 km (or more) from the main hospital and health care structures (DGR X/5208). Unsurprisingly, the amount of social and assistance services required and provided to support the difficult access to services increases year after year.

By assuming a social-ecological framework of analysis [9] the Place4Carers project (P4C) will disentangle the role of spaces and of their interrelated dynamics in the ageing process.

1. *ageing space as ecosystem: the uniqueness of ageing in rural and remote areas.* In the Italian context, similarly to other European countries, the elderly are becoming a prominent feature of the population, especially in rural and remote areas [10]. Literature suggests that inequities in access to health care systems for elderly people in rural and remote populations are more frequent compared to access in urban areas.[11]. Ageing societies present a range of challenges for the health and aged care system, particularly in rural and remote areas where workforce shortage and lack of access to specialist services are confounding factors. It is interesting to note that scientific literature has less focused on ageing population in rural and remote areas, even if these areas have more elders than urban areas. [12]. For these reasons, we can say that researches on ageing populations are urban biased. The need for health and social care related services in rural and remote areas has not been met by service provision delivered in urban contexts [11,13,14]. Research focusing on older persons living at the geographical and social peripheries, argue that in policy and economic debates the local experiences of older persons living in rural and remote communities have often been ignored [15,16]. The P4C project aims to address this gap.

2. *ageing space as mesosystem: opportunity and challenges of the "ageing-in-place" imperative.* "ageing-in-place" is a popular term in current ageing policy and is today recognized as a strategic priority for making the ageing process more sustainable for both individuals and societies[17–20]. "Ageing in place" is defined as "remaining living in the community, with some level of independence, rather than in residential care" [21]. Some researches highlighted that people prefer to age in place [1] because it has been shown that this strategy enables effectively older persons to maintain independence, autonomy, and meaningful relations in terms of connection to social support, including friends and family [22,23]. Promoting the aging-in-place reduces the

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11 economic expenditures of public institutions, impacting positively on governments, health and social care
12 organizations, elders and their family [23]. The term “place” has several dimensions that are interrelated: a
13 physical dimension that can be seen and touched like home or neighborhood, a social dimension involving
14 relationships with people and the ways in which individuals remain connected to others, an emotional and
15 psychological dimension, which has to do with a sense of belonging and attachment, and a cultural dimension,
16 which has to do with older people’s values, beliefs, ethnicity, and symbolic meanings. Sustainable
17 communities should offer affordable and holistic services and a continuum of care to effectively engage elderly
18 and their family in effective and sustainable health and social care, enabling them to ageing in health in place.
19 Several interventions and projects both at a national and international level aim to reduce the fragmentation of
20 welfare services by putting citizens – and their needs - at the centre of service delivery. However, a study
21 conducted in Europe [24] found that a fragmented system of services was unable to meet the holistic needs of
22 ageing societies, because the integration between social and health services is complex, including problems in
23 inter-disciplinary teamwork, financing, and legal aspects. Integration of health and social services is on the
24 agenda of many ageing countries [25]. Furthermore, in rural and remote context, welfare and social system
25 often results fragmented and poorly accessible, making the ageing in place a possible paradigm only with high
26 care out-of-pocket costs for families that have to take care alone of their elders. Few interventions devoted to
27 ageing in place are related to digital/telemedicine intervention, without regarding the social aspect of care [26].

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29 *3. ageing space as microsystem: the role of family relationship and caregiving for elderly citizens.* Family
30 caregiver engagement is indeed regarded as a key factor to improve the quality and the sustainability of care
31 services for the elderly [27–32]. Several studies have shown that caregivers are the invisible backbone of social
32 and health care settings, particularly in rural and remote areas, as they facilitate the integration especially in
33 areas and communities with limited access to services[33]. Despite their unquestionable role in increasing the
34 chance of ageing-in-place for the elderly people they take care of, the caregivers experience several criticalities
35 such as burden, social isolation and depletion. In fact, caregivers attest a critical decrease on their quality of
36 life [34], and they report health issues, such as tiredness, insomnia, depression, weight loss or gain, drug use
37 and need for psychological support [35]; these issues are frequently reported by women, especially if older.
38 The European Commission report on “The indirect cost of long term care” (2013) [36] reveals that situation
39 of psycho-social distress is widespread for caregivers not only in Italy but also in other countries. This is
40 especially the case for caregivers of elderly people [37] and for those who are required to dedicate a significant
41 amount of time to caring activities [37]. Actually, the caregivers of elderly people often become the primary
42 interlocutors for the health and social care services to take decisions over the patients’ therapies and long-term
43 treatments [38].

44 Moreover, caregivers support the compliance to treatments and therapies and they support the older persons in
45 managing follow-ups and clinical exams [39]. Last, caregivers are often the primary sources of psychological
46 support and empathy for the care receiver and for whom they represent the main reference. Against this
47 background, research shows that family caregivers who are more engaged in the care journey of their loved
48 one have more capability to deal with stressful situations such as caregiving and thus, have less anxiety and
49 depression and better perceived health [40–43]. By feeling more empowered and engaged in the caregiving
50 tasks, caregivers might also reach a better work-family balance.

51 Appropriate engagement and tailored support of caregivers have the potential to improve their experiences and
52 quality of life and facilitate shared decision making while enhancing the quality of care provided to older
53 persons and reducing the use of unnecessary health and social services [44], as well as increasing the
54 effectiveness of health and social care interventions [45]. Furthermore, supporting the role of informal carers
55 (i.e. family and friends providing mostly unpaid care to frail seniors) is important to provide an adequate
56 continuum of care between informal and formal care.

57 Figure 1 describes the threefold social-ecological framework of analysis adopted by P4C.

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Aims

The project aims to achieve the following objectives:

1. to explore, understand and measure caregiver' needs in terms of education, welfare, assistance and social inclusion and in relation to the services planned by the local home care agency, which is responsible for the delivery of basic social services and social assistance towards fragile people in the territory of Vallecamonica;
2. to assess the cost (both economic and social) sustained by families when caring for their elderly relatives and to understand the critical aspects faced when accessing and using welfare services that are present in the territory;
3. to co-produce a new - better accessible and sustainable - service targeted to family caregivers of elderly citizens on the basis of the participative cooperation among family caregivers, elderly citizens, researchers and welfare system representatives;
4. to test the transferability of the new service concept in other and similar rural and remote territories of the Lombardy Region (Italy).

METHODS AND ANALYSIS

Methodological approach

The proposed study is designed according to a Community Based Participatory Research (CBPR) approach [46,47], to engage and to capture the perspectives of all the relevant stakeholders involved in the home based service of long term care. Thanks to its participatory nature, the P4C project will be not only the occasion to deepen the ageing and caregiving **dynamics** in the specific outreach territory of Vallecamonica. It will also be an innovative co-productive setting, where to engage older citizens, their caregivers and the welfare system to generate ideas for more accessible, effective and economically sustainable welfare services targeted to family caregivers.

This approach has the value to be grounded in the needs of communities and of the community-based organizations that serve them. It will allow community transformation and social change by directly engaging target stakeholders and stakeholders' knowledge in the research process and its outcomes. This is a partnership approach to research that equitably involves community members, organizational representatives, and researchers in all the phases of the research process. In this approach, all partners contribute expertise and ownership to reach shared decisions and to make the knowledge produced best rooted in the community experience and more able to be translated into the practice of services development.

In this project, we will mainly focus on the community of Vallecamonica, with 41 municipalities, and twelve hundred thousands inhabitants, 19% over 65 years old [48], to deepen the unique experiences and needs of family caregivers caring for elderly citizens located in that geographic area. Moreover, the involvement of the local home care agency (ATSP) will be a key asset in this project, in order to produce knowledge well integrated with situated interventions and policies and thus better able to generate social change and to improve the health and quality of life of community members. The ATSP is a public agency that coordinates third parties in delivering services to fragile persons as old people, families, disabled people with professional social service. Community members, professionals belonging to home care agency and the researchers will collaborate in all the phases of the project in order to improve its sustainability and its ability to set the ground not only for a better knowledge production process, but also for the translation of such knowledge into a real opportunity for policy, organizational and social change. We will also guarantee the continuous methodological and scientific supervision of an International Advisory Board in order to validate the research design and the tools used in the research. An important aspect of this study is to provide insight from all the stakeholders' perspectives by involving them in all the phase of the research process.

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Study Design

The Place4Carer Research Protocol is articulated in 5 work packages (WPs), as described in the next paragraphs.

WP1 – Quantitative survey to define family caregivers needs, current services usage and sustained costs

Objectives. This research module is conceived as an extensive assessment on the entire population of family caregivers of elderly people receiving services from the ATSP in Vallecamonga aimed to:

- Analyze, quantify and map experiences, unmet needs, preferences and expectations of support and assistance of family caregivers involved in elderly care, in general and in relation to the specific service offered by ATSP;
- Perform a service and costs analysis in order to map the actual use of available services by caregivers and the direct costs sustained by families for the elderly care and support;
- Identify the main target of caregiver (i.e. the more needing ones) to which address the new service and to be involved in the following participatory phases of the project.

Tools and methods. A quantitative descriptive survey was designed comprehending measures of caregivers' needs, levels of engagement and questions to gather information about the direct costs sustained by the families for providing assistance to the elderly (i.e. out of pocket payments both for the services received by the ATSP and for additional assistance services). The survey was administered by a psychologist at caregivers' homes. The WP1 started in march 2018 and finished in June 2018.

Sampling. Only family caregivers that had concrete difficulties in the daily care of their care receivers were involved in the survey. We focused on caregivers whose elders had activated home-based long-term care services from two to 12 months [49] and had been living in Vallecamonga. Based on this constraint, the research identified five the local providers that were offering this type of services in the valley and expressly consented to participate in the project (i.e. ATSP and four rest houses). In doing so, the selecting criteria were: family caregivers, whose elders have been living at home in Vallecamonga and assisted from 2 to 12 months by one of the five home-based long-term care service providers involved in the project.

The overall number of family caregivers eligible for the study was around 321. We asked the five service providers to explain the research and its objectives to all eligible family caregivers and to collect their interest in the project. Since caregivers do not usually have the time nor the interest in explaining their personal condition to unknown parties [50], the sample size of family caregivers that are both eligible and interested in the research was quite limited: 147 caregivers. To increase the response rate, a psychologist contacted by phone all the caregivers of the sample to organize with them face-to-face meetings for submitting the survey. Despite this approach required time and resources, it reduced the number of bias that may arise during the self-administration of the questionnaire. We expected that the large majority of family caregiver have medium-low health literacy and education. Thus, the presence and assistance of a psychologist supported them in understanding and filling the questionnaire correctly, by reducing the number of missing data [51]. Based on this approach, we reached a satisfactory response rate of 45% [52]. Caregivers involved in this WP1 are invited to participate in WP3 for the co-creation of a new service.

Data Analysis. Survey data were anonymized, stored in an electronic database and shared with the research partners. The data collected in the survey were analyzed with the aim of taking a clear picture of the population of the family caregivers in the area, in terms of psycho-social needs, level of engagement, out-of-pocket expenditures for caregiving activities (e.g. drugs, private professional assistance, transportation) [53] and cost of time loss for employment, calculated as the time used by the family caregiver in caring activity multiplied by the average cost of an Italian professional caregiver [54]. We designed the questionnaire by using tested scales and clear and familiar terms. The analysis of data was organized in four main steps. First, we performed a preliminary data analysis by computing descriptive statistics, such as mean, median, mode and standard deviation of all variables of the questionnaire. Second, we carried out a confirmatory factor analysis that aimed

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11 at confirming the theoretical relationships between factors and their related variables of tested scales used in
12 the questionnaire. Third, we investigated the correlation between psycho-social needs, level of engagement
13 and economic expenditures. Finally, we performed a cluster analysis to identify sub-groups of caregivers that
14 had similarities in terms of psycho-social needs, level of engagement and economic expenditures. Overall, this
15 analysis helped us to understand the condition of caregivers by developing a taxonomy that cluster caregivers
16 with similar needs, level of engagement and economic expenditures.

17 **WP2 – Analysis of the literature to map existing initiatives and services for caregiver engagement**

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19 *Objective.* The aim of WP2 was to map the good practices described in the literature related to support and
20 engage family caregivers of elderly people in rural and remote settings. The WP2 started in May 2018, mapping
21 interventions published in scientific articles and finished in February 2019 with the acceptance of the scoping
22 review in a scientific journal.

23 *Tools and Methods.* WP2 adopted a scoping review approach as set out by Arksey and O'Malley (2005)[55].
24 We explored the conceptualization of ageing and of intervention mechanisms adopted to promote caregiver's
25 engagement which oriented such interventions. The following search-terms have been adopted: [(caregivers
26 OR family member*) AND (ageing OR elderly* OR old*) OR (patient*) AND (support OR intervention OR
27 program OR education OR counselling) AND (rural* OR mountain* OR "hard to reach"*)]. The terms
28 caregivers and family members was adopted in order to differentiate from professional, paid caregivers. The
29 terms patients or older people were included to indicate the care receiver. Moreover, we included the terms
30 support, intervention, program, education, counselling, in order to map a broader variety of initiatives. Finally,
31 as our primary interest is on hard to reach areas, we included the terms rural, mountain and hard to reach. We
32 originally included also the term remote, but the research did not give any new result, as the notion of remote
33 context is still not explored in literature research. We checked also qualitatively the results of the search string,
34 reading titles, abstracts and full text.

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36 This scoping review was carried throughout the following scientific databases: Scopus, Psych-Info, Cinhal,
37 Pubmed.

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39 *Data Analysis.* For the data analysis, we followed the Arksey & O' Malley approach[55]. All articles were
40 merged in a unique Excel database in order to remove duplicates. Secondly, titles and abstracts were checked
41 for the inclusion criteria, and in cases of ambiguity, also full texts were read in order to be sure for the inclusion.
42 Moreover, the reference list were screened in order to identify additional material. Our inclusion criteria were
43 related to data and language of publication, accessibility of full text and focus of intervention, type of
44 caregivers, age of care-receivers and context of intervention. Articles should be published from 2012,
45 recognized European Year of Active ageing, in English, and the full text must be accessible. We decided to
46 start from 2012 as, considering that year as starting date, we identified 2545 articles, a consistent result. Among
47 all the articles selected, no-one cited previously interventions. Moreover, articles must focus on interventions
48 during the planning, piloting, implementation or analysis of the results. Finally, receivers of these interventions
49 must be informal caregivers of family members. The care receivers, as mentioned before, should be over 60
50 years old. On the other side, exclusion criteria were applied to articles that reflect on the necessity to provide
51 intervention to caregivers, without providing a service, are not included. Finally, the geographical context of
52 the provided service must be a hard to reach area, including rural and remote or mountain area. Articles were
53 analyzed at two levels. (1) Intervention characteristics: objective of the intervention, characteristics of the
54 receiver (by type of patient), context of intervention, presence or absence of technologies, individual or group
55 setting, tools and duration of the intervention. More precisely, the retrieved studies were organized according
56 to their main objective (i.e. psychosocial interventions, educational interventions, organizational
57 interventions.) following the categorization of Roter et al (1998) [56]. (2) Study characteristics: country, study

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design (randomized controlled trial “RCT”, controlled trial “CT”, cross-sectional “CS”, pilot “P”), sample and number of participants, outcome measures and results.

WP3 – Co-creation workshop with caregivers

Objectives. This work package of the protocol is dedicated to co-design, co-manage and co-assess (together with family caregivers, service providers and researchers) new ideas about a new service. The objectives and features of the new service should be able to address caregivers’ needs and expectations that emerged in WP1 and take a cue from the good practices suggested by the results of the scoping literature review in WP2. This analysis is a unique opportunity for discussing with family caregivers on the challenges of the aging-in-place imperative in the context of rural and remote areas and co-designing, co-managing and co-assessment along all the phases of the project with them a possible solution. The WP3 started in July 2018 and is expected to finish by September 2020.

Sampling. Only family caregivers that highlighted their interest in the project during the WP1 are eligible to participate in the co-creation workshops. Thus, the selecting criteria are: family caregivers that participate in WP1 and whose elders have been living at home in Vallecacamonica and assisted by one of the five home-based long-term care service’s providers. A psychologist is inviting caregivers by phone by calling them on random order to arrive to an average of 8-10 participants for each workshop. To increase the participation rate, we are trying to invite 10 to 12 caregivers at each workshop, knowing that logistical difficulties often lead us to some abandonment. Based on literature suggestions and the sample dimension, we expect to organize a minimum of 3 to 6 co-creation workshops in the co-design, co-managing and co-assessment phases of the service cycle [57].

Tools and methods. We carry out co-creation workshops in three main phases of the service life cycle, i.e. design, managing and assessment. Each workshop lasts about 2 hours and is conducted by two researchers specifically trained in qualitative research. To include different point of view and enrich the discussions, the workshops involve both users (family caregivers) and service providers (ATSP). The workshops are audio recorded.

In the design phase of the service, we involved family caregivers to identify their needs and to co-design new services for supporting them. Researchers facilitate the co-design workshops using the following steps:

- Mutual acquaintance: presentation of the project, presentation of participants with their biographical info, and description of their role as informal caregiver;
- Focus on the needs: What are the difficulties of caregiving in the context of Vallecacamonica, for them and for their elders;
- Insights, ideas for the new service : starting from emerged needs, what are the caregiver ideas for a new service, with a particular attention on information, educational and psycho-social help;
- Conclusions: caregivers, together with the moderator and members of the team of research, try to merge ideas for the new service in a unique project idea and to define it accurately.

In the managing and assessment phases of the service, we involve family caregivers to collect their opinions about the service’s activities. While the caregivers’ feedbacks in the managing phase are used to improve the service’s activities currently underway, in the assessment phase they will support researchers in assessing the service after its conclusion. Researchers facilitate the co-managing and co-assessment workshops accomplishing the following steps:

- Mutual acquaintance: presentation of the results of ongoing service pilot, highlighting the number of activities, the participation and satisfaction rate of the caregivers involved;
- Opinions, feedbacks on the ongoing service: starting from service’s results, what are the caregiver suggestions for improving the ongoing service (i.e. co-managing phase) or for assessing the overall service results (i.e. co-assessment phase);

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- 10 • Conclusions: caregivers, together with the moderator and members of the team of research, try to make practical suggestions for improving the new service both during its implementation and after its conclusion.
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14 *Data Analysis.* All workshops will be transcribed and analyzed using content analysis [58,59] with an inductive approach [60]. Since we investigate a specific phenomenon (i.e. aging in place) by observing the behaviors of family caregivers, we prefer to adopt an open and flexible analysis of data [61]. We will start coding the transcripts by using an open coding approach and grouping relevant concepts in categories [62]. Then, we will investigate the relationships between categories and creating higher-order themes. The coding process will continue until all the relevant insights will be coded and data saturation will be reached [63]. To ensure the reliability of the analysis, two researchers will code the transcripts in parallel, analyzing and checking any inconsistency. Then, authors will discuss results and assemble the final set of categories in high-level themes that represent the main concepts of investigation [64]. Resulting themes and categories will be compared in term of similarities and differences with the results of WP1 and WP2 [65].

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24 **WP4 - Piloting and preliminary assessment**

25 *Objectives.* This WP is dedicated to the testing of the service ideas co-created in WP3 through a piloting action organized and delivered by ATSP. Specifically, the pilot study is aimed at:

- 28 • Assessing the feasibility and conditions for implementing the service in terms of effort and resources;
- 29 • Piloting the service;
- 30 • Evaluating the service.

31 The WP4 started in April 2019 and is expected to end by September 2020.

32 *Tools and methods.* To test services' ideas and to ensure the iterative improvement of the pilot, we are using a service prototyping approach [66]. Among the several prototyping techniques, we have chosen "The Service Prototyping Practical Framework" that guides researchers in service prototyping process through six steps. First, the research team have stated clearly the purpose of the service. Second, the team have defined the most suitable and effective way to use the resources and skills for the service's implementation [67]. To achieve this aim, we have performed a feasibility study for defining the capabilities and resources needed under legal, economic, operational, technical and scheduling point of view [68]. Third, the research team have chosen the most suitable technique for implementing the service, in line with team and users' knowledge and competences. Fourth, the team will define the drivers that evaluate the service resolution and quality. We will assess the pilot through a set of quantitative metrics suggested by the existing literature. For each activity of the pilot, we will identify the most appropriate set of indicators. Since the number of participants in this rural and remote area might not be very significant, we will integrate this quantitative data with interviews. Mixing both quantitative and qualitative data in a single study will allow us to improve the understanding of future issues related to the implementation of the pilot [69]. We will collect the opinion of the providers of the pilot with individual interviews. Fifth, the project team will have to verify the validity of the service prototyping by using the results of the pilot's assessment.

46 *Sample.* All the caregivers, whose elders are using at least one of the two type of homecare services identified in the WP1, are invited to participate to the pilot. We are spreading the project's activities and meetings through both online and offline channels, to include all caregivers that wish to participate. ATSP is in charge of the pilot delivery.

47 *Data Analysis.* Once we will have collect the assessment's results and the users' opinions on the service, we will try to generalize results proposing a set of barriers and enablers that may have limited or facilitated the implementation of the pilot. We will start listing all possible barriers and enablers that will arise from the

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analysis of the pilot. Then, we will compare them in term of differences, similarities, frequency of occurrence and consistency. Finally, we will discuss the final list with the research team and other stakeholders involved in the project in order to check the reliability of results.

WP5 Assessment of transferability to other regions and stakeholder involvement

Objectives. The transferability analysis, intends to make the insights and the idea of the new service better exportable to other similar extra-urban contexts. The transferability is assessed in Valtellina, which is an area geographically close to Vallecamonica and shares the same demographic challenges and similar difficulties in the access to assistance and services with the specific aim to:

- Investigate if the needs expressed by the family caregivers in mountainous and outreach communities are similar;
- Assess the transferability of the service ideas generated in WP 3;
- Engage stakeholders in the transferability, by adapting the service idea to the new specific context.

The WP5 started in December 2019 and is expected to end by December 2020.

Tools and methods. The module adopts a mixed methods design by using a qualitative study to integrate and deepen the previous quantitative one. In the first study, we will distribute an exploratory survey to the head of service providers in charge of social and welfare services for elders living in Valtellina. We will involve head of service providers because they know the territory and the needs of family caregivers, thus, they can give us an objective and valuable opinion on the P4C project and its implementation's effectiveness in Valtellina. The survey's aim is twofold. First, it checks the interests of the local districts in the project by investigating the correspondence with family caregivers' needs. Second, it intends to understand the future issues that may arise in adopting the project in the new context. Since we do not expect significant number of respondents, we will integrate survey's results by organizing focus groups with the providers of long-term household in the districts that express their interest in the study. The aim of this second qualitative study is to collect further insights about possible issues and barriers related to transferability of the project in that area. Based on surveys and focus groups' results, we will organize a feasibility study that will analyze legal, economic, operational, technical and scheduling constraints [70]. Even if in this project we will not deliver a new service in another territorial context, we want to put the basements for a transferability that could be done in another action research project.

Sample. At the beginning, we will present the pilot's activities and results to the professionals in charge of social and welfare services of local districts in Valtellina, collecting their interests in the project. We will involve and contact the districts interested in the project to discuss a possible transferability of the service in their territory. For each district that will give us its availability, we will organize a focus group inviting the operators and staff that are managing and providing long-term household services for elders. The direct involvement and interaction with professionals and operators that might be in charge to create the service will allow us to collect insights for adopting the service in the new context.

Data Analysis. Data from surveys and focus group will be triangulated with official and internal documentation related to the welfare systems in Valtellina [71]. Results of the assessment of transferability will be verified through interviews with key actors of the local districts of Valtellina for collecting their opinions and checking the reliability of results.

PATIENT AND PUBLIC INVOLVEMENT

Citizens and members of the public institutions are involved in P4C at various stages of the study. We are holding information/ discussion sessions with key community stakeholders (caregivers, elderly citizens, public institutions) to co-create the envisaged family caregiver services and recommendations across the spectrum of the project. This helps to create a positive and receptive environment for the ultimate implementation of the

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outputs of the project. The involvement in the research Protocol of representatives belonging to both private and public institutions is allowing us to create synergic exchange between stakeholders having different points of view and resulting in alignment and cohesion of approach, without compromising independence of any party. In particular, the involvement of ATSP of Vallecamonica in the project is guaranteeing the access to the field and a more “ecological” insight on the ageing and caring dynamics in this territory. It is also guaranteeing the more concrete applicability of the ideas of services developed with the real commitment of the key welfare actors in the territory.

This inclusion of patients/public in this way helps with enhanced recruitment and enables these participants to share their experiences of taking part with others and to underline the importance of the study to people like themselves. Finally, citizens and public representatives are actively involved in disseminating the results of the research.

PROJECT IMPLICATIONS AND FUTURE POLICY

The P4C mission is to enhance and sustain the role of family caregiver in making the “ageing in place” imperative a sustainable reality in rural and remote areas. The results of the project will contribute to deliver more value to elderly citizens and health and social system, while making the welfare processes more efficient. Furthermore, by enhancing the skills and the psychological wellbeing of family caregivers of elderly citizens, the project will also contribute to improve quality of life and social inclusion of the elderly loved ones. Existing knowledge on meaningful family caregiver engagement will be aligned, and sustainably implemented through involvement of relevant stakeholders. The P4C project will deliver a transformative network structure and instruments by creating the resources for making the current welfare system more responsive to the needs of elderly citizens and of their family caregivers. To serve this mission, the research is a multi-stakeholder, multi-level and self-sustained project, which will have both short-term and long-term beneficial effects, as outlined below. Furthermore, by the implementation of the sustainability strategy the long-term impact is that family caregiver engagement will be a common standard in the welfare ecosystem guided by commonly accepted practices. Moreover, the P4C protocol is expected to sensitize family caregiver about the available resources to be activated in the territory and how to make the healthcare/welfare process more fluid and less fragmented. This would also reduce the waste of health and social resources.

Overall, all the stakeholders involved in the project may benefit from each other’s expertise and develop a better understanding of how diverse viewpoints can positively drive and impact on successful ageing processes. The impact of this is mutual trust and understanding nurtured by both the P4C results and the participation in the project. The study might have also some limitation. The impact of Place4Carers activities should be conceivable as local. However, since it includes actions and strategies in order to assess the generalizability of the insights produced to other extra-urban contexts in Lombardy, we are going to have some insights about results’ exportability.

ETHICS AND DISSEMINATION

The study was approved by the Ethics Committees of both Università Cattolica del Sacro Cuore and Politecnico di Milano. Informed consent will be collected from all participants. Data will be treated in anonymized form and only the P4C research team will have access to the data.

The research team will provide a wide dissemination of the key achievements and recommendations to diverse stakeholders through various activities, thus supporting the impact of the project outcomes. Moreover, caregivers will be central to dissemination of the baseline information, which helped to motivate community involvement during and beyond the study.

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11 According to these premises, the aims of the dissemination activities will be: (1) to generate awareness about
12 the concept and the main aims of the project; (2) to ensure strategic and extensive outreach to the ageing
13 research community at large and engage with all other external relevant initiatives and projects to ensure
14 optimal synergies and cross-fertilization and avoid duplication of efforts; (3) to identify opportunities to
15 collaborate in developing a cohesive and coherent ecosystem to support possible next phases of the project, its
16 adoption and its sustainability.

17 **POTENTIAL LIMITATIONS**

18
19 The present protocol paper presents at least two possible limitations related to the target population chosen for
20 this study. First, we expect a small sample size in WP1, WP3 and WP4, due to the peculiarity of the rural and
21 remote context that limits the generalization of the research findings [72]. Second, the direct involvement in
22 the design phase of the service may influence its level of innovativeness. Since the target population have
23 medium-low level managerial or technological capabilities, we expect to identify low innovative service
24 solution that may not involve any usage of technology. However, we believe that the investigation of the
25 conditions of family caregivers in rural and remote areas is innovative 'per se' [12] and gives new insights
26 regarding the opinions of this marginalized population that are usually excluded from the regional and national
27 policies [73]. By explaining this protocol research, we would like to foster the investigation of marginalized
28 population in rural and remote areas for reducing the social, economic and health discrepancies with the urban
29 areas.

30
31 **Contributors** GG is the study principal investigator and contributed to develop the study design and to write
32 the protocol. SB, NM, CM, EG, AL, MC, VG, CF, RF contributed to develop the study design and to write the
33 protocol. All authors approved the final manuscript.

34
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37
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39
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41
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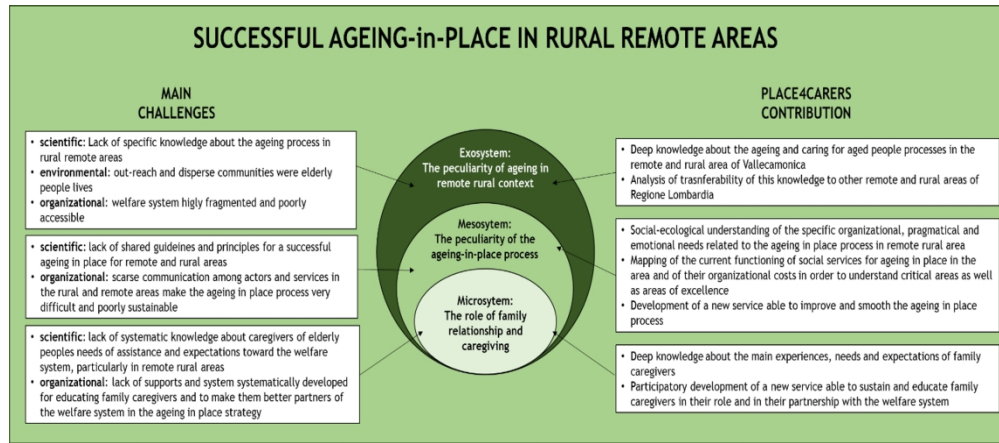
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A three-fold perspective on successful "ageing-in-place" processes

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PLACE4CARERS: A MIXED-METHOD STUDY PROTOCOL FOR ENGAGING FAMILY CAREGIVERS IN MEANINGFUL ACTIONS FOR SUCCESSFUL AGEING IN PLACE

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PLACE4CARERS:**A MIXED-METHOD STUDY PROTOCOL FOR ENGAGING FAMILY CAREGIVERS IN MEANINGFUL ACTIONS FOR SUCCESSFUL AGEING IN PLACE**

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Abstract

Introduction. Engaging family caregivers could be a critical asset to make the “ageing-in-place” imperative a reality. This is particularly evident in rural and remote areas, where caregivers can fill the gaps that exist due to the fragmentation of the welfare system. However, there is little knowledge about the expectations that family caregivers have towards healthcare services in rural and remote areas.

Place4Carers (P4C) project aims to co-produce an innovative organizational model of social and healthcare services for family caregivers of older citizens living in Vallecamonica (Italy). The project is expected to facilitate ageing-in-place for older citizens, thus helping caregivers in their daily care activities.

Methods and analysis. Place4Carers is a community-based participatory research project featuring 5 WPs. WP1 consisted of a survey of unmet needs of caregivers and older people receiving services in Vallecamonica. WP2 consisted of a scoping literature review to map services that provide interventions of support to caregivers living in remote areas and promote engagement. WP3 organizes co-creation workshops with caregivers to co-design, co-manage and co-assess ideas and proposals for shaping caregiver-oriented services and organizational models. WP3 enriches the results of WP1 (survey) and WP2 (scoping literature review) and aims to co-create new ideas for intervention support with and for caregivers in relation to the objectives, features and characteristics of a new service able to address the caregiver needs and expectations. WP4 tests the service ideas co-created in WP3 through piloting an intervention based on ideas co-created with caregivers. Finally, WP5 assesses the transferability of the intervention to other similar contexts.

Ethics and dissemination. The study has been approved by the Ethics Committees of the Department of Psychology of Università Cattolica del Sacro Cuore and Politecnico of Milan. Results will be disseminated through peer reviewed journals, scientific meetings and meetings with the general population.

Keywords: Caregiver engagement; Community based participatory research; service co-creation; ageing-in-place

Strengths and limitation of this study

- ▶ This study aims to use participatory methods to co-design an accessible and sustainable service for family caregivers of older citizens.
- ▶ Participation in the planning, design and implementation of the service will include family caregivers, older citizens, researchers and representatives from the welfare system (as ATSP, the agency that provide home services to local community).
- ▶ To our knowledge this is the first co-produced study that uses participatory methods to enhance and sustain the role of family caregivers to make ‘ageing in place’ a sustainable reality in rural and remote areas.
- ▶ The methodology of this study implies a multi-stakeholder, multi-level and self-sustainable approach, which will have both short-term and long-term beneficial effects on the possibility to continue the service deployment even after the end of the project
- ▶ Further studies are warranted to validate in other context the implied methodology

INTRODUCTION

Rationale of the study

This study's rationale is based on the insight that successful ageing is a complex phenomenon that is intrinsically intertwined with the 'places' and spaces that people belong to [1]. Spaces are not only a physical backdrop to events, but also have social, psychological and symbolic meanings[2]. People may have quite different lived experiences, expectations and opinions related to a particular space. None of these aspects of space (social, physical and symbolic) is necessarily more 'real' or important than any other. Instead, they are interconnected and directly dependent on each other [3]. Ageing is a dynamic process that is largely influenced by physical, social and cultural spaces [4]. Literature [5–8] discusses the concept of space in the ageing process from a three-fold perspective of (i) ageing spaces as eco systems, (ii) ageing spaces as meso-systems and (iii) ageing spaces as micro-systems. These inter-relationships are particularly noticeable in rural and remote areas. The research setting is Vallecamonica, an outreach territory in Italy and local partner is ATSP the agency that provide home services to local community.

Vallecamonica is a mountainous territory in the northern part of the Lombardy Region. It is divided into 44 municipalities, all of which have been categorized as "peripheral" or "ultra-peripheral", due to a poor access to services, scarce infrastructures, limited economic prosperity and negative demographic trends. Residential areas in Vallecamonica are geographically dispersed, and the viability is not made easy by the configuration of the territory and the limited network of infrastructures and public transportation services. The population living in the area is characterized by an ageing index, computed as the ratio between the number of people aged 65 or more and those aged 14 or less, equal to 157,3 (the average for the Lombardy Region is 152,6; DGR X/5208). The high proportion of elderly people attests a situation of a multidimension frailty, with several social and health care needs. Against this widespread need, most of the municipalities are distant 20 to 40 km (or more) from the main hospital and health care structures (DGR X/5208). Unsurprisingly, the amount of social and assistance services required and provided to support the difficult access to services increases year after year.

By assuming a social-ecological framework of analysis [9] the Place4Carers project (P4C) will disentangle the role of spaces and of their interrelated dynamics in the ageing process.

1. *ageing space as ecosystem: the uniqueness of ageing in rural and remote areas.* In the Italian context, similarly to other European countries, the elderly are becoming a prominent feature of the population, especially in rural and remote areas [10]. Literature suggests that inequities in access to health care systems for older people in rural and remote populations are more frequent compared to access in urban areas,[11]. Ageing societies present a range of challenges for the health and aged care system, particularly in rural and remote areas where workforce shortage and lack of access to specialist services are confounding factors. It is interesting to note that scientific literature has less focused on ageing population in rural and remote areas, even if these areas have more elders than urban areas. [12]. For these reasons, we can say that research on ageing populations are urban biased. The need for health and social care related services in rural and remote areas has not been met by service provision delivered in urban contexts [11,13,14]. Research focusing on older persons living at the geographical and social peripheries, argue that in policy and economic debates the local experiences of older persons living in rural and remote communities have often been ignored [15,16]. The P4C project aims to address this gap.

2. *ageing space as mesosystem: opportunity and challenges of the "ageing-in-place" imperative.* "ageing-in-place" is a popular term in current ageing policy and is today recognized as a strategic priority for making the ageing process more sustainable for both individuals and societies [17–20]. "Ageing in place" is defined as "remaining living in the community, with some level of independence, rather than in residential care" [21]. Some research highlighted that people prefer to age in place [1] because it has been shown that this strategy enables effectively older persons to maintain independence, autonomy, and meaningful relations in terms of connection to social support, including friends and family [22,23]. Promoting the aging-in-place reduces the

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3 economic expenditures of public institutions, impacting positively on governments, health and social care
4 organizations, elders and their family [23]. The term “place” has several dimensions that are interrelated: a
5 physical dimension that can be seen and touched like home or neighborhood, a social dimension involving
6 relationships with people and the ways in which individuals remain connected to others, an emotional and
7 psychological dimension, which has to do with a sense of belonging and attachment, and a cultural dimension,
8 which has to do with older people’s values, beliefs, ethnicity, and symbolic meanings. Sustainable
9 communities should offer affordable and holistic services and a continuum of care to effectively engage elderly
10 and their family in effective and sustainable health and social care, enabling them to ageing in health in place.
11 Several interventions and projects both at a national and international level aim to reduce the fragmentation of
12 welfare services by putting citizens – and their needs - at the centre of service delivery. However, a study
13 conducted in Europe [24] found that a fragmented system of services was unable to meet the holistic needs of
14 ageing societies, because the integration between social and health services is complex, including problems in
15 inter-disciplinary teamwork, financing, and legal aspects. Integration of health and social services is on the
16 agenda of many ageing countries [25]. Furthermore, in rural and remote context, welfare and social system
17 often results fragmented and poorly accessible, making the ageing in place a possible paradigm only with high
18 care out-of-pocket costs for families that have to take care alone of their elders. Few interventions devoted to
19 ageing in place are related to digital/telemedicine intervention, without regarding the social aspect of care [26].
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24 *3. ageing space as microsystem: the role of family relationship and caregiving for elderly citizens.* Family
25 caregiver engagement is indeed regarded as a key factor to improve the quality and the sustainability of care
26 services for older people [27–32]. Several studies have shown that caregivers are the invisible backbone of
27 social and health care settings, particularly in rural and remote areas, as they facilitate the integration especially
28 in areas and communities with limited access to services[33]. Despite their unquestionable role in increasing
29 the chance of ageing-in-place for the older people they take care of, the caregivers experience several
30 criticalities such as burden, social isolation and depletion. In fact, caregivers attest a critical decrease on their
31 quality of life [34], and they report health issues, such as tiredness, insomnia, depression, weight loss or gain,
32 drug use and need for psychological support [35]; these issues are frequently reported by women, especially if
33 older. The European Commission report on “The indirect cost of long term care” (2013) [36] reveals that
34 situation of psycho-social distress is widespread for caregivers not only in Italy but also in other countries.
35 This is especially the case for caregivers of older people [37] and for those who are required to dedicate a
36 significant amount of time to caring activities [37]. Actually, the caregivers of older people often become the
37 primary interlocutors for the health and social care services to take decisions over the patients’ therapies and
38 long-term treatments [38].
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40 Moreover, caregivers support the compliance to treatments and therapies and they support the older persons in
41 managing follow-ups and clinical exams [39]. Last, caregivers are often the primary sources of psychological
42 support and empathy for the care receiver and for whom they represent the main reference. Against this
43 background, research shows that family caregivers who are more engaged in the care journey of their loved
44 one have more capability to deal with stressful situations such as caregiving and thus, have less anxiety and
45 depression and better perceived health [40–43]. By feeling more empowered and engaged in the caregiving
46 tasks, caregivers might also reach a better work-family balance.
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48 Appropriate engagement and tailored support of caregivers have the potential to improve their experiences and
49 quality of life and facilitate shared decision making while enhancing the quality of care provided to older
50 persons and reducing the use of unnecessary health and social services [44], as well as increasing the
51 effectiveness of health and social care interventions [45]. Furthermore, supporting the role of informal carers
52 (i.e. family and friends providing mostly unpaid care to frail seniors) is important to provide an adequate
53 continuum of care between informal and formal care.
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55 Figure 1 describes the threefold social-ecological framework of analysis adopted by P4C.
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Aims

The project aims to achieve the following objectives:

1. to explore, understand and measure caregiver' needs in terms of education, welfare, assistance and social inclusion and in relation to the services planned by the local home care agency, which is responsible for the delivery of basic social services and social assistance towards fragile people in the territory of Vallecamonica;
2. to assess the cost (both economic and social) sustained by families when caring for their older relatives and to understand the critical aspects faced when accessing and using welfare services that are present in the territory;
3. to co-produce a new - better accessible and sustainable - service targeted to family caregivers of older citizens on the basis of the participative cooperation among family caregivers, older citizens, researchers and welfare system representatives;
4. to test the transferability of the new service concept in other and similar rural and remote territories of the Lombardy Region (Italy).

METHODS AND ANALYSIS

Methodological approach

The proposed study is designed according to a Community Based Participatory Research (CBPR) approach [46,47], to engage and to capture the perspectives of all the relevant stakeholders involved in the home based service of long term care. Thanks to its participatory nature, the P4C project will be not only the occasion to deepen the ageing and caregiving dynamics in the specific outreach territory of Vallecamonica. It will also be an innovative co-productive setting, where to engage older citizens, their caregivers and the welfare system to generate ideas for more accessible, effective and economically sustainable welfare services targeted to family caregivers.

This approach has the value to be grounded in the needs of communities and of the community-based organizations that serve them. It will allow community transformation and social change by directly engaging target stakeholders and stakeholders' knowledge in the research process and its outcomes. This is a partnership approach to research that equitably involves community members, organizational representatives, and researchers in all the phases of the research process. In this approach, all partners contribute expertise and ownership to reach shared decisions and to make the knowledge produced best rooted in the community experience and more able to be translated into the practice of services development.

In this project, we will mainly focus on the community of Vallecamonica, with 41 municipalities, and twelve hundred thousand inhabitants, 19% over 65 years old [48], to deepen the unique experiences and needs of family caregivers caring for elderly citizens located in that geographic area. Moreover, the involvement of the local home care agency (ATSP) will be a key asset in this project, in order to produce knowledge well integrated with situated interventions and policies and thus better able to generate social change and to improve the health and quality of life of community members. The ATSP is a public agency that coordinates third parties in delivering services to fragile persons as old people, families, disabled people with professional social service. Community members, professionals belonging to home care agency and the researchers will collaborate in all the phases of the project in order to improve its sustainability and its ability to set the ground not only for a better knowledge production process, but also for the translation of such knowledge into a real opportunity for policy, organizational and social change. We will also guarantee the continuous methodological and scientific supervision of an International Advisory Board in order to validate the research design and the tools used in the research. An important aspect of this study is to provide insight from all the stakeholders' perspectives by involving them in all the phase of the research process.

Study Design

The Place4Carer Research Protocol is articulated in 5 work packages (WPs), as described in the next paragraphs.

WP1 – Quantitative survey to define family caregivers needs, current services usage and sustained costs

Objectives. This research module is conceived as an extensive assessment on the entire population of family caregivers of elderly people receiving services from the ATSP in Vallecamonica aimed to:

- Analyze, quantify and map experiences, unmet needs, preferences and expectations of support and assistance of family caregivers involved in elderly care, in general and in relation to the specific service offered by ATSP;
- Perform a service and costs analysis in order to map the actual use of available services by caregivers and the direct costs sustained by families for the elderly care and support;
- Identify caregivers to be involved in the participatory phases of the project, specifically those with significant caregiving difficulties.

Tools and methods. A quantitative descriptive survey was designed comprehending measures of caregivers' needs, levels of engagement and questions to gather information about the direct costs sustained by the families for providing assistance to the elderly (i.e. out of pocket payments both for the services received by the ATSP and for additional assistance services). The survey was administered by a psychologist at caregivers' homes. The WP1 started in march 2018 and finished in June 2018.

Sampling. Only family caregivers that had concrete difficulties in the daily care of their care receivers were involved in the survey. We focused on caregivers whose elders had activated home-based long-term care services from two to 12 months [49] and had been living in Vallecamonica. Based on this constraint, the research identified five the local providers that were offering this type of services in the valley and expressly consented to participate in the project (i.e. ATSP and four rest houses). In doing so, the selecting criteria were: family caregivers, whose elders have been living at home in Vallecamonica and assisted from 2 to 12 months by one of the five home-based long-term care service providers involved in the project.

The overall number of family caregivers eligible for the study was around 321. We asked the five service providers to explain the research and its objectives to all eligible family caregivers and to collect their interest in the project. Since caregivers do not usually have the time nor the interest in explaining their personal condition to unknown parties [50], the sample size of family caregivers that are both eligible and interested in the research was quite limited: 147 caregivers. To increase the response rate, a psychologist contacted by phone all the caregivers of the sample to organize with them face-to-face meetings for submitting the survey. Despite this approach required time and resources, it reduced the number of bias that may arise during the self-administration of the questionnaire. We expected that the large majority of family caregiver have medium-low health literacy and education. Thus, the presence and assistance of a psychologist supported them in understanding and filling the questionnaire correctly, by reducing the number of missing data [51]. Based on this approach, we reached a satisfactory response rate of 45% [52]. Caregivers involved in this WP1 are invited to participate in WP3 for the co-creation of a new service.

Data Analysis. Survey data were anonymized, stored in an electronic database and shared with the research partners. The data collected in the survey were analyzed with the aim of taking a clear picture of the population of the family caregivers in the area, in terms of psycho-social needs, level of engagement, out-of-pocket expenditures for caregiving activities (e.g. drugs, private professional assistance, transportation) [53] and cost of time loss for employment, calculated as the time used by the family caregiver in caring activity multiplied by the average cost of an Italian professional caregiver [54]. We designed the questionnaire by using tested scales and clear and familiar terms. The analysis of data was organized in four main steps. First, we performed a preliminary data analysis by computing descriptive statistics, such as mean, median, mode and standard deviation of all variables of the questionnaire. Second, we carried out a confirmatory factor analysis that aimed

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3 at confirming the theoretical relationships between factors and their related variables of tested scales used in
4 the questionnaire. Third, we investigated the correlation between psycho-social needs, level of engagement
5 and economic expenditures. Finally, we performed a cluster analysis to identify sub-groups of caregivers that
6 had similarities in terms of psycho-social needs, level of engagement and economic expenditures. Overall, this
7 analysis helped us to understand the condition of caregivers by developing a taxonomy that cluster caregivers
8 with similar needs, level of engagement and economic expenditures.
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10 11 12 ***WP2 – Analysis of the literature to map existing initiatives and services for caregiver engagement*** 13

14 *Objective.* The aim of WP2 was to map the good practices described in the literature related to support and
15 engage family caregivers of elderly people in rural and remote settings. The WP2 started in May 2018, mapping
16 interventions published in scientific articles and finished in February 2019 with the acceptance of the scoping
17 review in a scientific journal.
18

19 *Tools and Methods.* WP2 adopted a scoping review approach as set out by Arksey and O'Malley (2005)[55].
20 We explored the conceptualization of ageing and of intervention mechanisms adopted to promote caregiver's
21 engagement which oriented such interventions. The following search-terms have been adopted: [(caregivers
22 OR family member*) AND (ageing OR elderly* OR old*) OR (patient*) AND (support OR intervention OR
23 program OR education OR counselling) AND (rural* OR mountain* OR "hard to reach"*)]. The terms
24 caregivers and family members was adopted in order to differentiate from professional, paid caregivers. The
25 terms patients or older people were included to indicate the care receiver. Moreover, we included the terms
26 support, intervention, program, education, counselling, in order to map a broader variety of initiatives. Finally,
27 as our primary interest is on hard to reach areas, we included the terms rural, mountain and hard to reach. We
28 originally included also the term remote, but the research did not give any new result, as the notion of remote
29 context is still not explored in literature research. We checked also qualitatively the results of the search string,
30 reading titles, abstracts and full text.
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33 This scoping review was carried throughout the following scientific databases: Scopus, Psych-Info, Cinhal,
34 Pubmed.
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38 *Data Analysis.* For the data analysis, we followed the Arksey & O' Malley approach[55]. All articles were
39 merged in a unique Excel database in order to remove duplicates. Secondly, titles and abstracts were checked
40 for the inclusion criteria, and in cases of ambiguity, also full texts were read in order to be sure for the inclusion.
41 Moreover, the reference list were screened in order to identify additional material. Our inclusion criteria were
42 related to data and language of publication, accessibility of full text and focus of intervention, type of
43 caregivers, age of care-receivers and context of intervention. Articles should be published from 2012,
44 recognized European Year of Active ageing, in English, and the full text must be accessible. We decided to
45 start from 2012 as, considering that year as starting date, we identified 2545 articles, a consistent result. Among
46 all the articles selected, no-one cited previously interventions. Moreover, articles must focus on interventions
47 during the planning, piloting, implementation or analysis of the results. Finally, receivers of these interventions
48 must be informal caregivers of family members. The care receivers, as mentioned before, should be over 60
49 years old. On the other side, exclusion criteria were applied to articles that reflect on the necessity to provide
50 intervention to caregivers, without providing a service, are not included. Finally, the geographical context of
51 the provided service must be a hard to reach area, including rural and remote or mountain area. Articles were
52 analyzed at two levels. (1) Intervention characteristics: objective of the intervention, characteristics of the
53 receiver (by type of patient), context of intervention, presence or absence of technologies, individual or group
54 setting, tools and duration of the intervention. More precisely, the retrieved studies were organized according
55 to their main objective (i.e. psychosocial interventions, educational interventions, organizational
56 interventions.) following the categorization of Roter et al (1998) [56]. (2) Study characteristics: country, study
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3 design (randomized controlled trial “RCT”, controlled trial “CT”, cross-sectional “CS”, pilot “P”), sample and
4 number of participants, outcome measures and results.
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8 **WP3 – Co-creation workshop with caregivers**

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10 *Objectives.* This work package of the protocol is dedicated to co-design, co-manage and co-assess (together
11 with family caregivers, service providers and researchers) new ideas about a new service. The objectives and
12 features of the new service should be able to address caregivers’ needs and expectations that emerged in WP1
13 and take a cue from the good practices suggested by the results of the scoping literature review in WP2. This
14 analysis is a unique opportunity for discussing with family caregivers on the challenges of the aging-in-place
15 imperative in the context of rural and remote areas and co-designing, co-managing and co-assessment along
16 all the phases of the project with them a possible solution. The WP3 started in July 2018 and is expected to
17 finish by September 2020.
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20 *Sampling.* Only family caregivers that highlighted their interest in the project during the WP1 are eligible to
21 participate in the co-creation workshops. Thus, the selecting criteria are: family caregivers that participate in
22 WP1 and whose elders have been living at home in Vallecamonica and assisted by one of the five home-based
23 long-term care service’s providers. A psychologist is inviting caregivers by phone by calling them on random
24 order to arrive to an average of 8-10 participants for each workshop. To increase the participation rate, we are
25 trying to invite 10 to 12 caregivers at each workshop, knowing that logistical difficulties often lead us to some
26 abandonment. Based on literature suggestions and the sample dimension, we expect to organize a minimum of
27 3 to 6 co-creation workshops in the co-design, co-managing and co-assessment phases of the service cycle
28 [57].
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31 *Tools and methods.* We will carry out co-creation workshops in three main phases of the service life cycle, i.e.
32 design, managing and assessment. Each workshop will last about 2 hours and will be conducted by two
33 researchers specifically trained in qualitative research. To include different point of view and enrich the
34 discussions, the workshops will involve both users (family caregivers) and service providers (ATSP). The
35 workshops will be audio recorded.
36

37 In the design phase of the service, we will involve family caregivers to identify their needs and to co-design
38 new services for supporting them. Researchers will facilitate the co-design workshops using the following
39 steps:

- 40 • Mutual acquaintance: presentation of the project, presentation of participants with their biographical
41 info, and description of their role as informal caregiver;
- 42 • Focus on the needs: What are the difficulties of caregiving in the context of Vallecamonica, for them
43 and for their elders;
- 44 • Insights, ideas for the new service : starting from emerged needs, what are the caregiver ideas for a
45 new service, with a particular attention on information, educational and psycho-social help;
- 46 • Conclusions: caregivers, together with the moderator and members of the team of research, try to
47 merge ideas for the new service in a unique project idea and to define it accurately.
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49 In the managing and assessment phases of the service, we will involve family caregivers to collect their
50 opinions about the service’s activities. While the caregivers’ feedback in the managing phase are used to
51 improve the service’s activities currently underway, in the assessment phase they will support researchers in
52 assessing the service after its conclusion. Researchers will facilitate the co-managing and co-assessment
53 workshops accomplishing the following steps:

- 54 • Mutual acquaintance: presentation of the results of ongoing service pilot, highlighting the number of
55 activities, the participation and satisfaction rate of the caregivers involved;
- 56 • Opinions, feedback on the ongoing service: starting from service’s results, what are the caregiver
57 suggestions for improving the ongoing service (i.e. co-managing phase) or for assessing the overall
58 service results (i.e. co-assessment phase);
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- Conclusions: caregivers, together with the moderator and members of the team of research, try to make practical suggestions for improving the new service both during its implementation and after its conclusion.

Data Analysis. All workshops will be transcribed and analyzed using content analysis [58,59] with an inductive approach [60]. Since we investigate a specific phenomenon (i.e. aging in place) by observing the behaviors of family caregivers, we prefer to adopt an open and flexible analysis of data [61]. We will start coding the transcripts by using an open coding approach and grouping relevant concepts in categories [62]. Then, we will investigate the relationships between categories and creating higher-order themes. The coding process will continue until all the relevant insights will be coded and data saturation will be reached [63]. To ensure the reliability of the analysis, two researchers will code the transcripts in parallel, analyzing and checking any inconsistency. Then, authors will discuss results and assemble the final set of categories in high-level themes that represent the main concepts of investigation [64]. Resulting themes and categories will be compared in term of similarities and differences with the results of WP1 and WP2 [65].

WP4 - Piloting and preliminary assessment

Objectives. This WP is dedicated to the testing of the service ideas co-created in WP3 through a piloting action organized and delivered by ATSP. Specifically, the pilot study is aimed at:

- Assessing the feasibility and conditions for implementing the service in terms of effort and resources;
- Piloting the service;
- Evaluating the service.

The WP4 started in April 2019 and is expected to end by September 2020.

Tools and methods. To test service ideas and to ensure the iterative improvement of the pilot, we are using a service prototyping approach [66]. Among the several prototyping techniques, we have chosen “The Service Prototyping Practical Framework” that guides researchers in service prototyping process through six steps. First, the research team have stated clearly the purpose of the service. Second, the team have defined the most suitable and effective way to use the resources and skills for the service’s implementation [67]. To achieve this aim, we have performed a feasibility study for defining the capabilities and resources needed under legal, economic, operational, technical and scheduling point of view [68]. Third, the research team have chosen the most suitable technique for implementing the service, in line with team and users’ knowledge and competences. Fourth, the team will define the drivers that evaluate the service resolution and quality. We will assess the pilot through a set of quantitative metrics suggested by the existing literature. For each activity of the pilot, we will identify the most appropriate set of indicators. Since the number of participants in this rural and remote area might not be very significant, we will integrate this quantitative data with interviews. Mixing both quantitative and qualitative data in a single study will allow us to improve the understanding of future issues related to the implementation of the pilot [69]. We will collect the opinion of the providers of the pilot with individual interviews. Fifth, the project team will have to verify the validity of the service prototyping by using the results of the pilot’s assessment.

Sample. All the caregivers, whose elders are using at least one of the two type of homecare services identified in the WP1, are invited to participate to the pilot. We are spreading the project’s activities and meetings through both online and offline channels, to include all caregivers that wish to participate. ATSP is in charge of the pilot delivery.

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3 *Data Analysis.* Once we will have collect the assessment's results and the users' opinions on the service, we
4 will try to generalize results proposing a set of barriers and enablers that may have limited or facilitated the
5 implementation of the pilot. We will start listing all possible barriers and enablers that will arise from the
6 analysis of the pilot. Then, we will compare them in term of differences, similarities, frequency of occurrence
7 and consistency. Finally, we will discuss the final list with the research team and other stakeholders involved
8 in the project in order to check the reliability of results.
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10 ***WP5 Assessment of transferability to other regions and stakeholder involvement***

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12 *Objectives.* The transferability analysis, intends to make the insights and the idea of the new service better
13 exportable to other similar extra-urban contexts. The transferability is assessed in Valtellina, which is an area
14 geographically close to Vallecamonica and shares the same demographic challenges and similar difficulties in
15 the access to assistance and services with the specific aim to:

- 16 • Investigate if the needs expressed by the family caregivers in mountainous and outreach communities
17 are similar;
- 18 • Assess the transferability of the service ideas generated in WP 3;
- 19 • Engage stakeholders in the transferability, by adapting the service idea to the new specific context.

20 The WP5 started in December 2019 and is expected to end by December 2020.
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23 *Tools and methods.* The module adopts a mixed methods design by using a qualitative study to integrate and
24 deepen the previous quantitative one. In the first study, we will distribute an exploratory survey to the head of
25 service providers in charge of social and welfare services for elders living in Valtellina. We will involve head
26 of service providers because they know the territory and the needs of family caregivers, thus, they can give us
27 an objective and valuable opinion on the P4C project and its implementation's effectiveness in Valtellina. The
28 survey's aim is twofold. First, it checks the interests of the local districts in the project by investigating the
29 correspondence with family caregivers' needs. Second, it intends to understand the future issues that may arise
30 in adopting the project in the new context. Since we do not expect significant number of respondents, we will
31 integrate survey's results by organizing focus groups with the providers of long-term household in the districts
32 that express their interest in the study. The aim of this second qualitative study is to collect further insights
33 about possible issues and barriers related to transferability of the project in that area. Based on surveys and
34 focus groups' results, we will organize a feasibility study that will analyze legal, economic, operational,
35 technical and scheduling constraints [70]. Even if in this project we will not deliver a new service in another
36 territorial context, we want to develop the foundation for a transferability plan that could be done in another
37 action research project.
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41 *Sample.* At the beginning, we will present the pilot's activities and results to the professionals in charge of
42 social and welfare services of local districts in Valtellina, collecting their interests in the project. We will
43 involve and contact the districts interested in the project to discuss a possible transferability of the service in
44 their territory. For each district that will give us its availability, we will organize a focus group inviting the
45 operators and staff that are managing and providing long-term household services for elders. The direct
46 involvement and interaction with professionals and operators that might be in charge to create the service will
47 allow us to collect insights for adopting the service in the new context.
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51 *Data Analysis.* Data from surveys and focus group will be triangulated with official and internal documentation
52 related to the welfare systems in Valtellina [71]. Results of the assessment of transferability will be verified
53 through interviews with key actors of the local districts of Valtellina for collecting their opinions and checking
54 the reliability of results.
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57 **PATIENT AND PUBLIC INVOLVEMENT**

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59 Citizens and members of the public institutions are involved in P4C at various stages of the study. We are
60 holding information/ discussion sessions with key community stakeholders (caregivers, elderly citizens, public

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3 institutions) to co-create the envisaged family caregiver services and recommendations across the spectrum of
4 the project. This helps to create a positive and receptive environment for the ultimate implementation of the
5 outputs of the project. The involvement in the research protocol of representatives belonging to both private
6 and public institutions is allowing us to create synergic exchange between stakeholders having different points
7 of view and resulting in alignment and cohesion of approach, without compromising independence of any
8 party. In particular, the involvement of ATSP of Vallecamonica in the project is guaranteeing the access to the
9 field and a more “ecological” insight on the ageing and caring dynamics in this territory. It is also guaranteeing
10 the more concrete applicability of the ideas of services developed with the real commitment of the key welfare
11 actors in the territory.
12

13 This inclusion of patients/public in this way helps with enhanced recruitment and enables these participants to
14 share their experiences of taking part with others and to underline the importance of the study to people like
15 themselves. Finally, citizens and public representatives are actively involved in disseminating the results of
16 the research.
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19 **PROJECT IMPLICATIONS AND FUTURE POLICY**

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22 The P4C mission is to enhance and sustain the role of family caregiver in making the “ageing in place”
23 imperative a sustainable reality in rural and remote areas. The results of the project will contribute to deliver
24 more value to elderly citizens and health and social system, while making the welfare processes more efficient.
25 Furthermore, by enhancing the skills and the psychological wellbeing of family caregivers of elderly citizens,
26 the project will also contribute to improve quality of life and social inclusion of the care receiver. Existing
27 knowledge on meaningful family caregiver engagement will be aligned, and sustainably implemented through
28 involvement of relevant stakeholders. The P4C project will deliver a transformative network structure and
29 instruments by creating the resources for making the current welfare system more responsive to the needs of
30 elderly citizens and of their family caregivers. To serve this mission, the research is a multi-stakeholder, multi-
31 level and self-sustained project, which will have both short-term and long-term beneficial effects, as outlined
32 below. Furthermore, by the implementation of the sustainability strategy the long-term impact is that family
33 caregiver engagement will be a common standard in the welfare ecosystem guided by commonly accepted
34 practices. Moreover, the P4C protocol is expected to sensitize family caregiver about the available resources
35 to be activated in the territory and how to make the healthcare/welfare process more fluid and less fragmented.
36 This would also reduce the waste of health and social resources.
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40 Overall, all the stakeholders involved in the project may benefit from each other’s expertise and develop a
41 better understanding of how diverse viewpoints can positively drive and impact on successful ageing processes.
42 The impact of this is mutual trust and understanding nurtured by both the P4C results and the participation in
43 the project. The study might have also some limitation. The impact of Place4Carers activities should be
44 conceivable as local. However, since it includes actions and strategies in order to assess the generalizability of
45 the insights produced to other extra-urban contexts in Lombardy, we are going to have some insights about
46 results’ exportability.
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50 **ETHICS AND DISSEMINATION**

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52 The study was approved by the Ethics Committees of both Università Cattolica del Sacro Cuore and
53 Politecnico di Milano. Informed consent will be collected from all participants. Data will be treated in
54 anonymized form and only the P4C research team will have access to the data.
55

56 The research team will provide a wide dissemination of the key achievements and recommendations to diverse
57 stakeholders through various activities, thus supporting the impact of the project outcomes. Moreover,
58 caregivers will be central to dissemination of the baseline information, which helped to motivate community
59 involvement during and beyond the study.
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3 According to these premises, the aims of the dissemination activities will be: (1) to generate awareness about
4 the concept and the main aims of the project; (2) to ensure strategic and extensive outreach to the ageing
5 research community at large and engage with all other external relevant initiatives and projects to ensure
6 optimal synergies and cross-fertilization and avoid duplication of efforts; (3) to identify opportunities to
7 collaborate in developing a cohesive and coherent ecosystem to support possible next phases of the project, its
8 adoption and its sustainability.
9

10 11 12 **POTENTIAL LIMITATIONS** 13

14 The present protocol paper presents at least two possible limitations related to the target population chosen for
15 this study. First, we expect a small sample size in WP1, WP3 and WP4, due to the peculiarity of the rural and
16 remote context that limits the generalization of the research findings [72]. Second, the direct involvement in
17 the design phase of the service may influence its level of innovativeness. Since the target population have
18 medium-low level managerial or technological capabilities, we expect to identify low innovative service
19 solution that may not involve any usage of technology. However, we believe that the investigation of the
20 conditions of family caregivers in rural and remote areas is innovative 'per se' [12] and gives new insights
21 regarding the opinions of this marginalized population that are usually excluded from the regional and national
22 policies [73]. By explaining this protocol research, we would like to foster the investigation of marginalized
23 population in rural and remote areas for reducing the social, economic and health discrepancies with the urban
24 areas.
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29 **Contributors** GG is the study principal investigator and contributed to develop the study design and to write
30 the protocol. SB, NM, CM, EG, AL, MC, VG, CF, RF contributed to develop the study design and to write the
31 protocol. All authors approved the final manuscript.
32

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35

36 **Competing interests** None declared.
37

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39

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41

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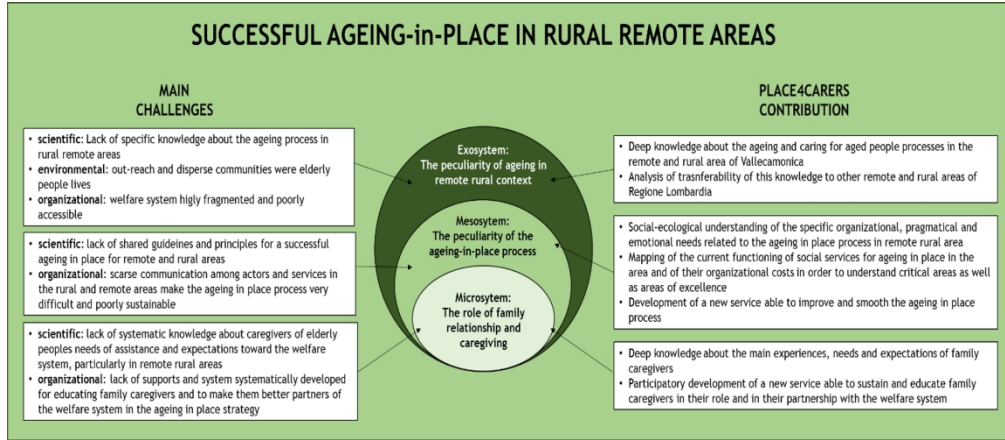
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A three-fold perspective on successful "ageing-in-place" processes

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