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# BMJ Open

## A Search for relevant Contextual Factors in Intervention Studies, a Stepwise Approach with Online Information.

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4 **Information.**  
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## Abstract

**Objective:** The aim of the present study is to describe a stepwise approach to study which contextual factors might moderate the effect of healthcare interventions and to test the feasibility of this approach within the D-SCOPE project.

**Design:** Exploratory case study

**Setting:** In the D-SCOPE project a complex intervention by means of home visits was set up to improve the access to tailored care in 3 municipalities (Ghent, Knokke-Heist and Tienen).

**Methods:** A five-step approach was designed and tested: (1) a theoretical/conceptual discussion of relevant contextual factor domains was held; (2) a search was done to find appropriate web-based public datasets which covered these topics with standardized information; (3) a list of all identified contextual factors was made (inventory); (4) to reduce the long list of contextual factors, a concise list of the most relevant contextual factors was developed based on the opinion of two independent reviewers; and (5) a Nominal Grouping Technique was applied.

**Results:** Three public web-based datasets were found resulting in an inventory of 157 contextual factors. After the selection by two independent reviewers, 41 contextual factors were left over and presented in the Nominal Grouping Technique which selected 10 contextual factors. The NGT included seven researchers, all familiar with the D-SCOPE intervention, with various educational backgrounds and expertise and lasted approximately one hour

**Conclusion:** The present study shows that the five-step approach is feasible to determine relevant contextual factors that might affect the results of an intervention study. Such information may be used to correct for in the statistical analyses and for interpretation of the outcomes of intervention studies.

## Key words

Context – online information – complex intervention – frailty – method

## Article Summary:

### Strengths and limitations of this study

- The role of the context within intervention studies is often ignored
- The world wide web offers an opportunity for to study the setting of an intervention
- The present study offers a uniform and standardized way based on five steps
- An in-depth study of the local context using online databases is feasible
- The present approach only presents a fraction of the context and not the full context of a study

## Introduction

Randomized controlled trials (RCTs) are widely regarded as the gold standard to identify causal relations between interventions and their predetermined outcomes. Some critics argue that, with respect to randomized trials of complex public health interventions, researchers fail to address the interaction of intervention components with each other and with the local context [1-3]. In the literature, the concept 'context' refers to the spatial and institutional locations of social situations, with the inherent norms, values, and interrelationships and describes those features of the conditions in which programs are introduced [1, 3]. The key features of complex interventions are: 1) the number of interacting components (the number and complexity of behaviors required by those delivering or receiving the intervention), 2) the number of groups or organizational levels targeted by the intervention, 3) the number and variability of outcomes, and 4) the degree of flexibility or tailoring of the intervention permitted [4]. As interventions are almost always introduced into diverse contexts (e.g., municipalities, neighborhoods, clinics), the mechanisms activated by the intervention will vary according to the saliently different context conditions. Because of the relevant variations in context and mechanisms activated by an intervention, its result is liable to have mixed outcome patterns [1]. In RCTs of complex interventions, the role of implementers, the local context, and other factors, that may moderate the effect of an intervention, often are ignored [2, 5]. Some authors argue that certain contexts are supportive to the intervention and some are not [1]. The need for including contextually relevant factors was also highlighted in 'The National Care For Elderly Programme' (2008-2016), a countrywide government-funded program in the Netherlands. Its goal was to develop a more proactive, integrated health-care system for older adults. More than 70 scientific projects were conducted, including nine large-scale trials. None of these nine proactive primary-care programs demonstrated clinically relevant effects on daily functioning. After the evaluation of these trials, one of the conclusions was the need to pay more attention to the in-depth analysis of the context and to develop a uniform methodology to study the local context in a standardized way [6]. Currently, more attention is given to the importance of context and the understanding of the context in complex interventions [7-8]. Several guidances have been developed to support researchers during the design of a complex intervention and to take the context into account [7-10]. One can use a wide range of research methods to gain a better understanding of the context in which the intervention will operate, although the focus is on qualitative methods and less on quantitative methods [7-8]. Nowadays, a significant amount of information can be found online, which was not available or difficult to find in the past. The World Wide Web could offer an opportunity for researchers to study the setting of an intervention. However, it is unknown whether the information available online is useful to study and compare the local contexts.

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3 The present study is framed within the Detection, Support and Care for Older People: Prevention and  
4 Empowerment (D-SCOPE) project and features an organized trial that was aimed to enable older adults  
5 to age well in place. After the baseline assessment, older participants assigned to the experimental  
6 group were contacted for a home visit by a professional from the social service of the municipality.  
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8 During the home visit, the professional from the social service of the municipality explored the older  
9 adult's competences, needs and preferences. The professional from the social service of the  
10 municipality proposed a type of intervention based on the results of the baseline assessment and the  
11 home visit. In consultation with the participant and social network, decisions with regard to tailored  
12 care and support were made. The intervention depended on the availability of the care and support  
13 services in the municipality, and could be formal (e.g., home care) or informal (e.g., activities of an  
14 older adult's association). A professional from the social service of the municipality monitored which  
15 care the participant received, whether the older person canceled the care and support and if the care  
16 recipient was satisfied with the supplied care. This was assessed monthly by telephone. The trial was  
17 performed in three municipalities [11]. As a part of the D-SCOPE project, we wanted to know which  
18 contextual factors might interact/moderate the effect of a home visit and its related tailored care and  
19 support. This information can be useful in explaining the results of the D-SCOPE intervention study and  
20 provide insight regarding which context might be supportive for a home visit and which might not.  
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22 The aim of the present study is to describe an approach to study which contextual factors might  
23 moderate the effect of healthcare interventions, and to test this approach for the D-SCOPE  
24 intervention. As web-based public data are generally easily obtainable, we focus on context data from  
25 such resources. To determine the feasibility of an in-depth study of the local context, the following  
26 research questions are answered: 1) are there relevant standardized web-based public data available  
27 in these three municipalities? and 2) how can the contextual factors most likely to interact with the  
28 intervention and moderate its outcomes be determined?  
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## 45 **Methods**

### 46 **Design**

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48 To test the feasibility of determining relevant contextual factors in a RCT, an exploratory case study  
49 was conducted within the D-SCOPE project [11]. This D-SCOPE trial was performed in three  
50 municipalities in the Flemish region in Belgium (Ghent, Knokke-Heist and Thienen, see supplementary  
51 file 1: Map of Flanders). Therefore, only the contextual factors of these three municipalities were  
52 considered. The different steps of the approach to determine the relevant contextual factors that  
53 might moderate the effects of health care interventions are hereby described.  
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**Five-step approach:**

Because of the complex nature of its intervention and depending on the availability of the care and support services in the municipality, the effect may be context-sensitive [12-14]. To determine the relevant contextual factors within the D-SCOPE project, five steps were taken (see Figure 1).

In the first step, a theoretical/conceptual discussion of the relevant contextual factor domains was held. A meeting (by the first, second and last author) was organized to discuss the topics that should be covered with regard to the D-SCOPE intervention; which features the data must fulfill to be included. The meeting was organized based on the results of the meta-analysis of Van der Elst et al. [5] and the professional experience of the two co-authors (the second and last author). Several inclusion and exclusion criteria, such as the exclusion of factors only related to children, such as childcare or crèches, were formulated [5].

In step two, after determining which topics should be covered, an explorative online search was performed (by the first author) to find appropriate and relevant public web-based datasets, which included the general contextual factors discussed in step one (e.g., datasets including official statistics).

In step three, after determining the appropriate public web-based datasets, an inventory of the contextual factors retrieved from the public datasets was made (by the first author). Regarding the availability of services, the inventory was based on the frameworks of official organizations. Microsoft Excel and the technique of mind mapping was used to construct the inventory. Mind mapping was used to structure and compare the available services in the three municipalities.

In step four, to reduce the number of contextual factors, a (critical) selection of the collected contextual factors was made by two experienced clinicians in primary care (the second and last author). Both received the inventory with the contextual factors and its distributions and were asked to assign each contextual factor a green, orange or red score, independently of each other. A green score indicated that the contextual factor might moderate the effect of the D-SCOPE intervention. An orange score reflected the opinion that one was not sure if the contextual factor might moderate the effect of the D-SCOPE intervention. A red score indicated that the contextual factor was not considered able to moderate the effect of the D-SCOPE intervention. The contextual factors assigned a green score by both reviewers were included in the fifth step; those factors with only red scores were automatically excluded. Regarding the status of all other contextual factors, and in the case of discrepancies, a meeting was held (between the first, second and last author) to reach consensus.

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5 In the fifth and last step, in order to determine the most relevant contextual factors a Nominal  
6 Grouping Technique (NGT) was applied [15]. The NGT included seven researchers of the D-SCOPE  
7 Consortium, all familiar with the D-SCOPE intervention, with various educational backgrounds and  
8 expertise (e.g., nurse, psychologist, educational scientist) and lasted approximately one hour. NGT is a  
9 highly structured method in decision-making and contains five parts: 1) generating ideas: the  
10 participants received the inventory of the contextual factors and its distributions. Each participant was  
11 asked to write down the contextual factors that might influence the outcome of a home visit (to keep  
12 it concise a maximum of ten), and had to motivate why these factors were chosen. The participants  
13 registered them without discussion; 2) recording ideas: the participants then shared their ideas and  
14 motivations with the group, without discussion; 3) discussing/clarifying ideas: in this phase, the  
15 participants discussed the contextual factors and the motivations of choosing them; 4) voting/rating  
16 ideas: after discussion, every participant was asked to register those contextual factors (maximum of  
17 10) that might influence the results of a home visit and rank them; and lastly, 5) summing the ratings:  
18 a list of the ten highest ranked contextual factors was made. The NGT method overcomes the problem  
19 of reluctance in participants who might be less willing to suggest ideas because of concerns of being  
20 criticized or creating conflict in groups [16-18].  
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### 33 **Patient and public involvement**

34 The study presents analysis of secondary data. There was no patient and public involvement.  
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38 **Add Figure 1:** Flow chart of the five-step approach to determine assumedly the most relevant  
39 contextual factors  
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## Results

Below, the results of the five-step approach applied within the D-SCOPE project are presented.

### Step 1: Theoretical/conceptual discussion of relevant contextual factor domains

The aim of the intervention was to detect frail older people, improve their access to tailored care and support, and facilitate aging well in place. Therefore, the research team decided that the retrieved information should cover sociodemographic, socioeconomic contextual factors, factors related to care supply/availability or care use, and factors related to the local government. Moreover, it was determined that these contextual factors should focus on older adults (aged 60 years and older) and that the public web-based dataset should use standardized data (e.g., official statistics) of the three municipalities of the D-SCOPE trial.

### Step 2: Explorative search for public datasets

Three suitable online public web-based datasets were identified in the selected municipalities: (1) the “InterMutualistic Agency” database, (2) the “Local Statistics” database, and (3) the “Social Map” database. In the “InterMutualistic Agency” database the data of seven Belgian health insurance institutions were collected and stored. The “Local Statistics” database is a portal site in which all types of statistics regarding the local and provincial administrations have been collected. The “Social Map” database collects data from health care organizations (broad interpretation) in a structured database. additional information regarding the databases can be found in supplementary file 2: Databases.

### Step 3: Inventory of the retrieved contextual factors

In total, 157 contextual factors were retrieved from the aforementioned datasets: 70 contextual factors were derived from the “InterMutualistic Agency” database, 36 contextual factors were derived from the “Local Statistics” database and 51 contextual factors were derived from the “Social Map” database. These contextual factors covered a broad range of information regarding the municipalities, including sociodemographic, socioeconomic, local governmental information, and data on care supply/availability. Microsoft Excel was used to list the contextual factors and its distributions. Since the “Social Map” lists all organizations and describes the services they offer, the technique of mind mapping was used to structure and compare the available services in the municipalities (supplementary 3: Mind Mapping). To categorize the availability of care and support in the municipality, the framework of the agency “Zorg en Gezondheid” (Care and Health) was used. This framework includes 12 domains, such as home care, geriatric care, and hospitals, as well as several

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3 subdomains of each domain. The agency “Zorg en Gezondheid” was founded by the Flemish authorities  
4 and its main task is the organization of care and support [19].  
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#### 8 Step 4: Critical selection 9

10 In total, two reviewers (the second and last author) independently selected 41 of the 157 contextual  
11 factors, that were presented during the NGT. Eighty-five contextual factors received a red score (do  
12 not moderate the effect of the intervention) by both reviewers, while 28 were assigned a green score  
13 (might moderate the effect of the intervention) by the reviewers. All other factors were discussed  
14 (between the first, second and last author) until consensus was reached. The final inventory of  
15 contextual factors included nine factors of the ‘InterMutualistic Agency’ database, seven contextual  
16 factors were derived from the “Local Statistics” database, and 25 of the “Social Map” database.  
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#### 23 Step 5: Nominal Grouping Technique 24

25 During the NGT, the list of the remaining contextual factors (see step 4) was presented. First, all  
26 participants were given 10 minutes to go through the list of contextual factors and their distribution.  
27 The participants were then asked to register the most relevant factors according to their opinions  
28 including motivating why. Secondly, the participants were asked to share their most relevant factors  
29 and motivation, without any discussion. This task required 15 minutes. Thirdly, a discussion of  
30 approximately 30 minutes was held. Fourthly, a voting was organized and the results were counted  
31 (step 5). In total, 20 of the 41 contextual factors presented in the NGT received votes. Within the D-  
32 SCOPE project, the aim was to retrieve a concise list of contextual factors. Therefore, table 1 presents  
33 those contextual factors with the highest scores (10) after voting in the NGT, together with the data of  
34 the three municipalities (derived from the three aforementioned databases). According to the  
35 participants of the NGT, those ten contextual factors were likely the most important moderators of  
36 the D-SCOPE intervention. The number of contextual factors on the list is purely meant to illustrate the  
37 approach; further research should determine whether the selected contextual factors are moderating  
38 the D-SCOPE trial. The dependency ratio (age 65+/20-64) had the highest score of all the contextual  
39 factors.  
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Table 1. Ten contextual factors and their distribution after Nominal Grouping Technique†

	Contextual factors	Ghent	Knokke-Heist	Thienen	Rank	Score
Sociodemographic contextual factors	1) Age 80+/total population 2015	5.0%	9.6%	6.6%	3	38
	2) Dependency ratio (65+/20-64 years) 2015	27.0%	63.1%	36.2%	1	64
	3) % age 65+ and living alone 2014	29.9%	30.7%	27.7%	6	30
Socioeconomic contextual factors	4) Percentage of beneficiaries aged 65 + and entitled to a guaranteed income	6.9%	5.5%	4.1%	3	38
	5) Underprivileged index (= % of births in underprivileged families in year 2014)	22.6%	13.6%	11.9%	5	32
	6) Percentage of beneficiaries entitled to additional compensation in Public health insurance	18.5%	12.9%	14.6%	9	20
Community resources	7) Total resources of the community social security in euros per inhabitant 2013 (in euro)	304	151	229	10	8
Availability of community health care centers	8) Community center	Yes	No	Yes	2	46
	9) 24/24 care	Yes	No	Yes	8	25
	10) Center for mental health care	Yes	No	Yes	7	24

Note: †The ten highest scoring contextual factors determined in the Nominal Grouping Technique, rank and score.

## Discussion

In RCTs of complex interventions, the role of the local context which may moderate the effect of an intervention, is often ignored. Therefore, an in-depth analysis of the context is needed. However, it was unknown whether it is feasible to construct an in-depth study of the local context with online information. The present research has shown that based, on a five-step approach an in-depth study of context using online data(bases) is feasible. The results have shown that a large amount of standardized data (contextual factors) is accessible on public web-based datasets. The five-step approach seems useful to collect and select the relevant contextual factors that might influence the outcome of such intervention.

A first key finding is the large amount of standardized public information/data currently available online (e.g., official statistics) which offers an opportunity for researchers. These web-based datasets cover a broad range of domains, including sociodemographic, and socioeconomic data, and data related to care supply and availability of care, which were considered important in the context of the D-SCOPE program that was the point of departure in the present study. The approach that was adopted in the current study makes it possible for future research to have a comprehensive understanding of the setting in which a healthcare intervention is implemented. However, the amount and type of information identified may differ depending on country/region and topic of study. For instance, in the D-SCOPE project the inventory contextual factors consisted of 157 factors.

Since a large amount of online information is available, one can assume that not all of this information is useful. Therefore, a systematic approach is essential to construct a concise list of contextual factors. A second result of the present study therefore, is the five-step approach as described in the methods that was used to identify relevant contextual factors. The discussion section within the NGT (step 5) can be used to formulate hypotheses and may help to explain the final results of the intervention. For instance, during the discussion in the NGT it was argued that the availability of a community center would have a moderating effect in the D-SCOPE intervention because it is important for social participation and organizing activities, but it also provides information, educational activities, meals and helps people to refer to other care and support services ('snowball-effect'). The lack of a community center in Knokke-Heist made it impossible for the professional of the social service center to refer participants towards other care and support services.

Thirdly, as a result of the five-step approach, it was revealed that in the D-SCOPE program, large differences were found between the three municipalities (Ghent, Knokke-Heist and Thienen). Socio-demographically, Knokke-Heist had the oldest population, with a dependency ratio (65+/20-64y) of 63.1% compared to 27.03% in Ghent and 36.21% in Thienen. In Knokke-Heist, the percentage of adults older than 80 years of age was almost twice as high compared to Ghent, while the total resources of

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3 community social security in euros per inhabitant in the year 2013 was only half of the budget in Ghent.  
4 These differences in contextual settings between the three municipalities may moderate the effect of  
5 the D-SCOPE intervention on its outcomes and emphasizes the relevance of the context. For instance,  
6 a previous systematic review by Stuck et al. concluded that preventive home visits reduce mortality in  
7 a younger study population (mean age < 80 years) but not in older populations [20].  
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### 13 **Strengths and limitations**

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15 The present study has several strengths. First, the present study gives a systematic approach to  
16 investigate the local context in an easy-to-apply way. Second, previous studies have shown that the  
17 NGT is a valid method in decision-making, based on the expertise of experienced researchers [16-17].  
18 The NGT made it feasible to reduce a long inventory of contextual factors to a short and concise list  
19 with the assumedly most relevant ones.  
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23 Our study also has some limitations. First, according to the socioecological model, context can be  
24 divided into various layers: microsystem, mesosystem, exosystem and macrosystem. The present  
25 study solely focuses on the level of the municipality and not on the individual or the cultural level. For  
26 example, no information is found regarding the relevant contextual factors, such as the level of  
27 coordination between and within services/institutions, or the norms and values within/between  
28 municipalities [21]. Secondly, the present information was retrieved from three public web-based  
29 datasets. The correctness of the analysis depends on the correctness and accuracy of those datasets  
30 (e.g., for many contextual factors the latest update was in 2014-2015, although the intervention study  
31 started in 2017). Thirdly, regardless of the large amount of information that can be found online, it is  
32 plausible that a significant amount of relevant information is still missing. For instance, we are aware  
33 that Knokke-Heist does not have a community center; however, no information is available regarding  
34 the activities organized by local organizations or other initiatives organized by the municipality that  
35 could function as an alternative for a community center. Fourthly, several aspects of the 5-step  
36 approach are based on experts' opinions (e.g., part four and five). This indicates the assumption that  
37 the D-SCOPE trial can interact with the selected contextual factors. However, further evidence-based  
38 research is needed.  
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### 52 **Implications and future research**

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54 New innovations and technologies offer opportunities for contemporary and future scientists. Before  
55 the existence of the World Wide Web, constructing an inventory of contextual factors in different  
56 communities would be a considerable and time-consuming challenge. Today, a substantial amount of  
57 information can be found in online-standardized datasets. This enables future intervention studies to  
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3 take the local context into account. For instance, the present results can be useful to explain  
4 differences in the effects of the D-SCOPE intervention in the three municipalities and provide insight  
5 regarding the contexts that might be supportive for a home visit and those that are not. For instance,  
6 older adults in need of extra social contact and participation could not be referred to a community  
7 center in Knokke-Heist, when this is possible in Ghent and Thienen, where a community center is  
8 available. The lack of a community center in Knokke-Heist could impact how the D-SCOPE intervention  
9 affected its outcomes. Based on these insights of the present study, new (theory-driven) hypotheses  
10 can be formulated that can be tested, giving a better understanding of the mechanisms related to an  
11 intervention. Therefore, we would advise researchers to perform an in-depth analysis of the context  
12 before the start of an intervention to avoid post-hoc data-driven analysis in the urge to explain the  
13 results. In case an intervention study includes many municipalities, a contextual factor can also be used  
14 as moderator in the statistical model. For instance, the availability of a community center could be an  
15 independent dummy variable in the statistical analysis.

16  
17 Because of the proposed five-step approach, future RCTs could meet the criticism of lack of attention  
18 to the context when evaluating an intervention [1]. This five-step approach can also be used for  
19 interventions with other topics (e.g., economic research, criminology) or research for other purposes;  
20 for instance, the risk stratification of areas whereby the characteristics (e.g., sociodemographic,  
21 socioeconomic, care supply) of a village, municipality or city are assessed and compared to macro-level  
22 data to determine the local (health) needs and challenges [22, 23].

## 33 34 35 36 37 **Conclusion**

38 Some authors argue that certain contexts are supportive for the implementation of an intervention  
39 and some are not, although the role of the context is often ignored in RCTs [1]. The present study  
40 shows that it is feasible to perform an in-depth analysis of a local context. A significant amount of  
41 information is available online and an easy-to-apply five-step approach can determine the assumedly  
42 most relevant contextual factors. With this five-step approach, future intervention studies can  
43 consider the local context when examining the effect of an intervention and formulate theory-driven  
44 hypotheses in RCTs. This should give us a better understanding of the effect of an intervention and the  
45 mechanisms related to the intervention.  
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### Author Contributions

All authors contributed to the design of the D-SCOPE intervention. The present study within the D-SCOPE trial was conceived by MVDE, JS, GK, JDL and BS. MVDE developed the inventory and wrote the first draft of the manuscript. LDD, BF, EDR, DD participated in the NGT and contributed to the data-analysis. All authors critically revised the manuscript and reviewed and approved the final manuscript.

All authors comply with the conditions of authorship according to the ICMJE

**Declaration of interests:** none

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**Data sharing statement:** all data are online available at the websites of the databases

**Ethics Statement:** The study presents an approach to search for contextual factors and apply this in the D-SCOPE trial, thereby we only used secondary data. Therefore, an ethical approval is not applicable.

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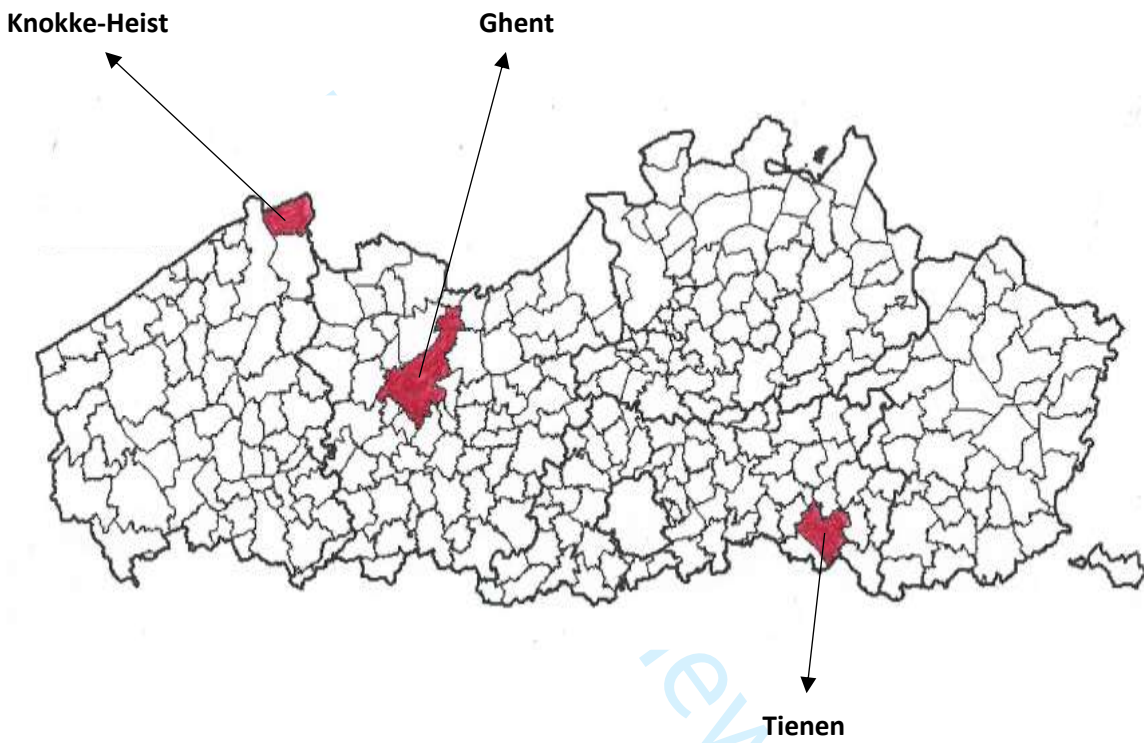
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**Appendix 1: Map of Flanders in Belgium**

The three municipalities participating in the D-SCOPE programme are Knokke-Heist, Ghent and Tienen.



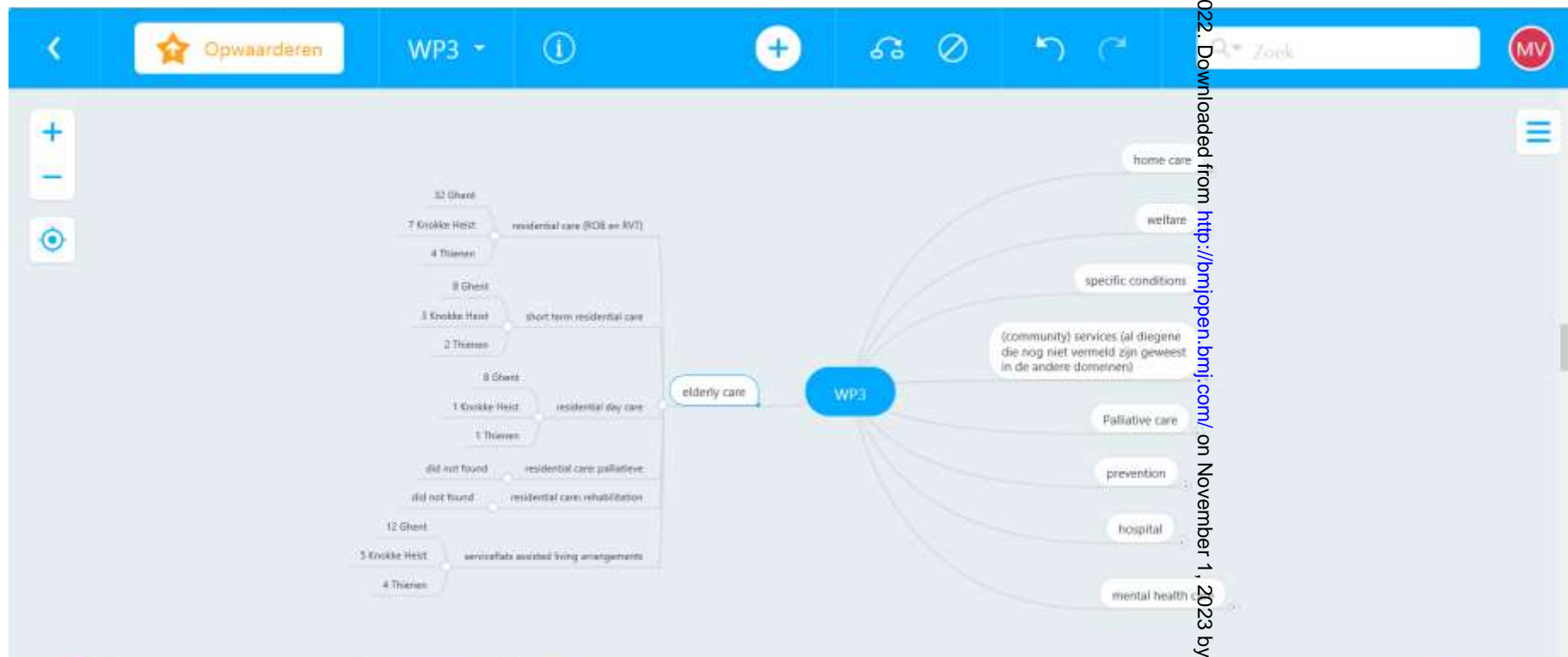
## Appendix 2: Databases

**InterMutualistic Agency (IMA):** The IMA collects, manages, and stores the data of the seven Belgian health insurance institutions. Examples of data are percentages of people age 75 or more with chronic illnesses, percentage of people aged 65 or more which make use of day care. The IMA Atlas (website) is an open-source database with health contextual factors. IMA analyzes the data on its own initiative or at the request of other partners. Its aim is to preserve or to improve the performance, the quality, and the accessibility of the Belgian health care system and health insurance.

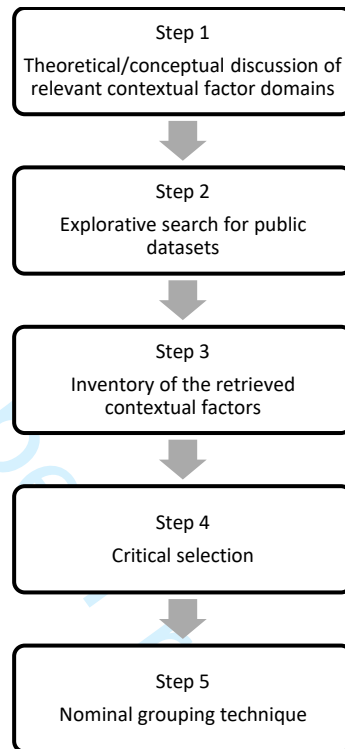
**Local Statistics:** The Local Statistics website is a joint venture between the Study Center of the Flemish Government, the Agency for Local Government, the Association of Flemish Cities and Municipalities, the Association of Flemish Provinces and the Flemish Community Commission of Brussels. It is a portal site where all types of statistics about local and provincial administrations such as number of people aged 65 and more, total resources of the community social security in euros per inhabitant 2013 (in euro) have been collected. Databases from various policy domains of the Flemish government are brought together.

**Social Map:** The Social Map database collects data from health care organizations (broad interpretation) in a structured database. It contains contact details, qualitative information such as target groups, opening hours, etc. Social Map aims to guide people in need of specific care to the appropriate organization

### Appendix 3: Mind mapping



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3 **Figure 1: Flow chart of the five-step approach to determine assumedly the most relevant contextual**  
4 **factors**  
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## STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1-2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	6
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	/
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	/
Bias	9	Describe any efforts to address potential sources of bias	/
Study size	10	Explain how the study size was arrived at	/
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	/
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	/
		(b) Describe any methods used to examine subgroups and interactions	/
		(c) Explain how missing data were addressed	/
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	/
		(e) Describe any sensitivity analyses	/

Continued on next page

<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	/
		(b) Give reasons for non-participation at each stage	/
		(c) Consider use of a flow diagram	15
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	/
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	/
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	/
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	8-9
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	/
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-9
		(b) Report category boundaries when continuous variables were categorized	/
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	/
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	/
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).

# BMJ Open

## A Search for relevant Contextual Factors in Intervention Studies, a Stepwise Approach with Online Information.

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Secondary Subject Heading:	Evidence based practice, Public health
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4 **Information.**  
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For peer review only

## Abstract

**Objective:** The aim of the present study is to describe a stepwise approach to study which contextual factors might moderate the effect of healthcare interventions and to test feasibility of this approach within the D-SCOPE project.

**Design:** Exploratory case study

**Setting:** In the D-SCOPE project a complex intervention by means of home visits was set up to improve access to tailored care in 3 municipalities (Ghent, Knokke-Heist and Tienen).

**Methods:** one designed and tested an approach including five steps: (1) a theoretical/conceptual discussion of relevant contextual factor domains was held; (2) a search was done to find appropriate web-based public datasets which covered these topics with standardized information; (3) a list of all identified contextual factors was made (inventory); (4) to reduce the long list of contextual factors, a concise list of most relevant contextual factors was developed based on the opinion of two independent reviewers; and (5) a Nominal Grouping Technique was applied.

**Results:** Three public web-based datasets were found resulting in an inventory of 157 contextual factors. After the selection by two independent reviewers, 41 contextual factors were left over and presented in a Nominal Grouping Technique which selected 10 contextual factors. The NGT included seven researchers, all familiar with the D-SCOPE intervention, with various educational backgrounds and expertise and lasted approximately one hour

**Conclusion:** The present study shows that a five-step approach is feasible to determine relevant contextual factors that might affect the results of an intervention study. Such information may be used to correct for in the statistical analyses and for interpretation of the outcomes of intervention studies.

## Key words

Context – online information – complex intervention – frailty – method

## Article Summary:

### Strengths and limitations of this study

- The role of context within intervention studies is often ignored
- The world wide web offers an opportunity for to study the setting of an intervention
- The present study offers a uniform and standardized way based on five steps
- An analysis of the local context using online databases is feasible
- The present approach only presents a fraction of context and not the full context of a study

## Introduction

Randomized controlled trials (RCTs) are widely regarded as gold standard to identify causal relations between interventions and their predetermined outcomes. Some critics argue that, with respect to randomized trials of complex public health interventions, researchers fail to address the interaction of intervention components with each other and with the local context [1-3]. In literature, the concept 'context' refers to spatial and institutional locations of social situations, with the inherent norms, values, and interrelationships and describes those features of the conditions in which programs are introduced [1, 3]. Key features of complex interventions are: 1) the number of interacting components (the number and complexity of behaviors required by those delivering or receiving the intervention), 2) the number of groups or organizational levels targeted by the intervention, 3) the number and variability of outcomes, and 4) the degree of flexibility or tailoring of the intervention permitted [4]. As interventions are almost always introduced into diverse contexts (e.g., municipalities, neighborhoods, clinics), the mechanisms activated by an intervention will vary according to the saliently different context conditions. Because of relevant variations in context and mechanisms activated by an intervention, its result is liable to have mixed outcome patterns [1]. In RCTs of complex interventions one often ignores the role of implementers, the local context, and other factors that may moderate the effect of an intervention [2, 5]. Some authors argue that certain contexts are supportive to the intervention and some are not [1]. The need for including contextually relevant factors was also highlighted in 'The National Care For Elderly Programme' (2008-2016), a countrywide government-funded program in the Netherlands. Its goal was to develop a more proactive, integrated health-care system for older adults. One conducted more than 70 scientific projects, including nine large-scale trials. None of these nine proactive primary-care programs demonstrated clinically relevant effects on daily functioning. After a process evaluation, the authors concluded that in research more attention should be given towards contextual factors and the need to develop a uniform methodology to study the local context in a standardized way [6]. Currently, more attention is given to the importance of context and the understanding of context in complex interventions [7-8]. Several guidances exist to support researchers during the design of a complex intervention and to take context into account [7-10]. A wide range of research methods can be used to gain a better understanding of context in which an intervention operates, although the focus is on qualitative methods and less on quantitative methods [7-8]. Nowadays, a significant amount of information can be found online, which was not available or difficult to find in the past. The World Wide Web could offer an opportunity for researchers to study the setting of an intervention. However, it is unknown whether the information available online is useful to study and compare local contexts.



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3 The present study is part of the Detection, Support and Care for Older People: Prevention and  
4 Empowerment (D-SCOPE) project, which features an organized trial that aimed to enable older adults  
5 to age well in place in three municipalities in Flanders (Belgium). After the baseline assessment, a  
6 professional from the social service of the municipality contacted participants assigned to the  
7 experimental for a home visit. During the home visit, the professional explored the older adult's  
8 competences, needs and preferences. The professional proposed a type of intervention based on the  
9 results of the baseline assessment and home visit. In consultation with the participant, decisions were  
10 made with regard to tailored care and support. The intervention depended on the availability of care  
11 and support services in the municipality, and could be formal (e.g., home care) or informal (e.g.,  
12 activities of an older adult's association). A professional from the social service of the municipality  
13 monitored which care the participant received. A professional of the municipality contacted every  
14 month all participants in the experimental group by phone. The aim of the contact was: 1) to verify  
15 whether the extra care and support was initiated and still ongoing, 2) to identify new care needs, 3) to  
16 assess the participants' satisfaction of the given care and support [11]. As a part of the D-SCOPE  
17 project, we wanted to know which contextual factors might interact/moderate the effect of a home  
18 visit and its related tailored care and support. This information can be useful in explaining the results  
19 of the D-SCOPE intervention study and provide insight regarding which context might be supportive  
20 for a home visit and which might not.

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22 In the present study we describe an approach to study which contextual factors might moderate the  
23 effect of healthcare interventions, and to apply this approach for the D-SCOPE intervention. As web-  
24 based public data are generally easily obtainable, we focus on context data from such resources. To  
25 determine feasibility to analyze local context, following research questions are answered: 1) are there  
26 relevant standardized web-based public data available in these three municipalities? and 2) how can  
27 the contextual factors most likely to interact with the intervention and moderate its outcomes be  
28 determined?

## 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 **Methods**

### 48 49 **Design**

50 To test feasibility of determining relevant contextual factors in a RCT, one conducted an exploratory  
51 case study of the Three municipalities within the D-SCOPE project [11]. The participating municipalities  
52 in the D-SCOPE trial are Ghent, Knokke-Heist and Thienen, in Flanders (see supplementary file 1: Map  
53 of Flanders). Therefore, only contextual factors of these three municipalities were considered. In what  
54 follows, one describes the different steps of the approach:  
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**Five-step approach:**

Because of the complex nature of its intervention and depending on the availability of care and support services in the municipality, the effect may be context-sensitive [12-14]. To determine relevant contextual factors within the D-SCOPE project, five steps were taken (see Figure 1).

Add Figure 1: Flow chart of the five-step approach to determine assumedly the most relevant contextual factors

**Step 1: Theoretical/conceptual discussion of relevant contextual factor domains**

The authors (first, second and last) organized a meeting to discuss topics that should be covered with regard to the D-SCOPE intervention, meaning which features the data should fulfill to be included. The motivation to organize the meeting was based on the results of the meta-analysis of Van der Elst et al. [5] and professional experience of the two co-authors (the second and last author). In preparation of this meeting the first author searched for scientific approaches to take into account the context in an intervention study and studies concerning contextual factors. Based on this literature several inclusion and exclusion criteria were formulated such as the exclusion of factors only related to children, such as childcare or crèches [5].

**Step 2: Explorative search for public datasets**

To find appropriate and relevant public web-based datasets, the first author did an explorative search online. To be appropriate, public web-based databases had to include data concerning the topics as described in step one and meet the inclusion criteria. In the search of databases, we focused on governmental websites and scientific research institutes related to the Belgian/Flemish government (e.g., KCE, WIV). Afterwards, the first author did a google search using terms like official statistics, local data(bases), data(bases) municipalities.

**Step 3: Inventory of the retrieved contextual factors**

In step three, after determining the appropriate public web-based datasets, the first author made an inventory of contextual factors retrieved from the public datasets. Thereby each municipality was a column and each variable was a row (see table 1). Contextual factors were separately categorized within a topic (e.g. sociodemographic, socioeconomic). Regarding the availability of services, the inventory was based on the frameworks of official organizations. We used Microsoft Excel and the

technique of mind mapping to construct the inventory. Mind mapping was used to structure and compare the available services in the three municipalities (see supplementary file 2: Mind mapping).

Table 1: Inventory list

Topic	Variable	Municipality 1	Municipality 2	Municipality 3
Topic 1	variable 1			
	variable 2			
	variable X			
Topic 2	variable 1			
	variable 2			
	variable X			
Topic X	variable 1			
	variable 2			
	variable X			

#### Step 4: Critical selection

To reduce the number of contextual factors, two experienced clinicians in primary care (the second and last author) made a first (critical) selection. Both received the inventory with contextual factors and its distributions. They assigned each contextual factor a green, orange or red score, independently of each other. A green score indicated that a contextual factor might moderate the effect of the D-SCOPE intervention. An orange score reflected the opinion that one was not sure if a contextual factor might moderate the effect of the D-SCOPE intervention. A red score indicated that a contextual factor was not considered able to moderate the effect of the D-SCOPE intervention. Contextual factors assigned a green score by both reviewers were included in the fifth step; those factors with only red scores were automatically excluded. The first author organized a meeting with both authors to reach consensus regarding all other contextual factors.

#### Step 5: Nominal Grouping Technique

In order to determine the most relevant contextual factors, the first author organized a Nominal Grouping Technique (NGT) [15]. The NGT included seven researchers of the D-SCOPE Consortium, all familiar with the D-SCOPE intervention, with various educational backgrounds and expertise (e.g., nurse, psychologist, educational scientist) and lasted approximately one hour. NGT is a highly structured method in decision-making and contains five parts (see Figure 2): 1) generating ideas: the participants received the inventory of contextual factors and its distributions. Each participant was asked to write down the contextual factors that might influence the outcome of a home visit and had to motivate why these factors were chosen. To keep it concise, the participants were asked to limit the

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3 number of factors up to ten. The participants registered them without discussion; 2) recording ideas:  
4 the participants then shared their ideas and motivations with the group, without discussion; 3)  
5 discussing/clarifying ideas: in this phase, the participants discussed the contextual factors and the  
6 motivations of choosing them; 4) voting/rating ideas: after discussion, every participant was asked to  
7 register those contextual factors (maximum of 10) that might influence the results of a home visit and  
8 rank them; and lastly, 5) summing the ratings: a list of the ten highest ranked contextual factors was  
9 made. The NGT method overcomes the problem of reluctance in participants who might be less willing  
10 to suggest ideas because of concerns of being criticized or creating conflict in groups [16-18].  
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18 Add Figure 2: Flow chart Nominal grouping technique  
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### 21 **Patient and public involvement** 22

23 The study presents analysis of secondary data. There was no patient and public involvement.  
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## Results

In what follows, one presents the results of the five-step approach applied within the D-SCOPE project.

### Step 1: Theoretical/conceptual discussion of relevant contextual factor domains

The aim of the intervention was to detect frail older people, improve their access to tailored care and support, and facilitate aging well in place. Therefore, the research team decided that the retrieved information should cover sociodemographic, socioeconomic contextual factors, factors related to care supply/availability or care use, and factors related to the local government. Moreover, one determined that: 1) Contextual factors should focus on older adults (aged 60 years and older); 2) The public web-based dataset should use standardized data (e.g., official statistics) of the three municipalities of the D-SCOPE trial.

### Step 2: Explorative search for public datasets

Three suitable online public web-based datasets were identified in the selected municipalities: (1) the “InterMutualistic Agency” database, (2) the “Local Statistics” database, and (3) the “Social Map” database. The “InterMutualistic Agency” database collects the data of seven Belgian health insurance institutions. The “Local Statistics” database is a portal site in which all types of statistics regarding the local and provincial administrations have been collected. The “Social Map” database collects data from health care organizations (broad interpretation) in a structured database. Additional information regarding the databases can be found in supplementary file 3: Databases.

### Step 3: Inventory of the retrieved contextual factors

The inventory included 157 contextual factors, retrieved from the aforementioned datasets: 70 contextual factors derived from the “InterMutualistic Agency” database, 36 contextual factors derived from the “Local Statistics” database and 51 contextual factors were derived from the “Social Map” database. These contextual factors covered a broad range of information regarding the municipalities, including sociodemographic, socioeconomic, local governmental information, and data on care supply/availability. Microsoft Excel was used to enlist contextual factors and its distributions. Since the “Social Map” lists all organizations and describes the services they offer, the technique of mind mapping was used to structure and compare the available services in the municipalities (supplementary file 2: Mind Mapping). To categorize the availability of care and support in the municipality, the framework of the agency “Zorg en Gezondheid” (Care and Health) was used. This framework includes 12 domains, such as home care, geriatric care, and hospitals, as well as several

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3 subdomains of each domain. The agency “Zorg en Gezondheid” was founded by the Flemish authorities  
4 and its main task is the organization of care and support [19].  
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#### 8 Step 4: Critical selection 9

10 In total, two reviewers (the second and last author) independently selected 41 of the 157 contextual  
11 factors, that were presented during the NGT. Eighty-five contextual factors received a red score (do  
12 not moderate the effect of the intervention) by both reviewers, while 28 were assigned a green score  
13 (might moderate the effect of the intervention) by the reviewers. All other factors were discussed  
14 (between the first, second and last author) until consensus was reached (supplementary file 4: critical  
15 selection). The final inventory of contextual factors included nine factors of the ‘InterMutualistic  
16 Agency’ database, seven from the “Local Statistics” database, and 25 of the “Social Map” database.  
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#### 23 Step 5: Nominal Grouping Technique 24

25 During the NGT, the list of the remaining contextual factors (see step 4) was presented. First, all  
26 participants had 10 minutes to go through the list of contextual factors and their distribution and to  
27 indicate the most relevant factors according to their opinions including motivating why. Secondly, all  
28 participants shared their most relevant factors and motivation, without any discussion. This task  
29 required 15 minutes. Thirdly, the participants held a discussion of approximately 30 minutes. Fourthly,  
30 the participants voted and afterwards the results were counted (step 5). In total, 20 of the 41  
31 contextual factors presented in the NGT received votes. Within the D-SCOPE project, the aim was to  
32 retrieve a concise list of contextual factors. Therefore, table 2 presents those contextual factors with  
33 the highest scores (10) after voting in the NGT, together with the data of the three municipalities  
34 (derived from the three aforementioned databases). According to the participants of the NGT, those  
35 ten contextual factors were likely the most important moderators of the D-SCOPE intervention. The  
36 number of contextual factors on the list is purely meant to illustrate the approach; further research  
37 should determine whether the selected contextual factors are moderating the D-SCOPE trial. The  
38 dependency ratio (age 65+/20-64) had the highest score of all the contextual factors.  
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Table 2. Ten contextual factors and their distribution after Nominal Grouping Technique†

	Contextual factors	Ghent	Knokke-Heist	Thienen	Rank	Score
Sociodemographic contextual factors	1) Age 80+/total population 2015	5.0%	9.6%	6.6%	3	38
	2) Dependency ratio (65+/20-64 years) 2015	27.0%	63.1%	36.2%	1	64
	3) % age 65+ and living alone 2014	29.9%	30.7%	27.7%	6	30
Socioeconomic contextual factors	4) Percentage of beneficiaries aged 65 + and entitled to a guaranteed income	6.9%	5.5%	4.1%	3	38
	5) Underprivileged index (= % of births in underprivileged families in year 2014)	22.6%	13.6%	11.9%	5	32
	6) Percentage of beneficiaries entitled to additional compensation in Public health insurance	18.5%	12.9%	14.6%	9	20
Community resources	7) Total resources of the community social security in euros per inhabitant 2013 (in euro)	304	151	229	10	8
Availability of community health care centers	8) Community center	Yes	No	Yes	2	46
	9) 24/24 care	Yes	No	Yes	8	25
	10) Center for mental health care	Yes	No	Yes	7	24

Note: †The ten highest scoring contextual factors determined in the Nominal Grouping Technique, rank and score.

## 1 Discussion

2 In RCTs of complex interventions one often ignores the role of the local context which may moderate  
3 the effect of an intervention. Therefore, more attention should be given to contextual factors in the  
4 design and analysis of complex interventions. However, it remained unclear whether it is feasible to  
5 explore and analyze the local context with online information. The present study shows that based, on  
6 a five-step approach an analysis of the context using online data(bases) is possible. The results show  
7 that a large amount of standardized data (contextual factors) is accessible on public web-based  
8 datasets. The five-step approach seems useful to collect and select relevant contextual factors that  
9 might influence the outcome of an intervention applied in a specific context.

10 A first key finding is the large amount of standardized public information/data currently  
11 available online (e.g., official statistics) which offers an opportunity for researchers. These web-based  
12 datasets cover a broad range of topics, such as sociodemographic data, socioeconomic data,  
13 information related to the availability of care support services (these data were considered important  
14 in the context of the D-SCOPE program). The adopted approach in the present study makes it possible  
15 for future research to have a more comprehensive understanding of the setting in which a healthcare  
16 intervention is implemented. However, the amount and type of information identified may differ  
17 depending on country/region and topic of study. For instance, in the D-SCOPE project the inventory  
18 contextual factors consisted of 157 factors.

19 Since a large amount of online information is available, one can assume that not all of this information  
20 is useful. Therefore, a systematic approach is essential to construct a concise list of contextual factors.

21 A second result of the present study therefore, is the five-step approach as described in the methods  
22 that was used to identify relevant contextual factors. The discussion section within the NGT (step 5)  
23 can be used to formulate hypotheses and may help to explain the final results of the intervention. For  
24 instance, during the discussion in the NGT it was argued that the availability of a community center  
25 would have a moderating effect in the D-SCOPE intervention because it is important for social  
26 participation and organizing activities, but it also provides information, educational activities, meals  
27 and helps people to refer to other care and support services ('snowball-effect'). The lack of a  
28 community center in Knokke-Heist made it impossible for the professional of the social service center  
29 to refer participants towards other care and support services.

30 Thirdly, as a result of the five-step approach, it was revealed that in the D-SCOPE program, large  
31 differences were found between the three municipalities (Ghent, Knokke-Heist and Thienen). Socio-  
32 demographically, Knokke-Heist had the oldest population, with a dependency ratio (65+/20-64y) of  
33 63.1% compared to 27.03% in Ghent and 36.21% in Thienen. In Knokke-Heist, the percentage of adults  
34 older than 80 years of age was almost twice as high compared to Ghent, while the total resources of



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3 35 community social security in euros per inhabitant in the year 2013 was only half of the budget in Ghent.  
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5 36 These differences in contextual settings between the three municipalities may moderate the effect of  
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7 37 the D-SCOPE intervention on its outcomes and emphasizes the relevance of context. For instance, a  
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9 38 previous systematic review by Stuck et al. concluded that preventive home visits reduce mortality in a  
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11 39 younger study population (mean age < 80 years) but not in older populations [20].  
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### 41 **Strengths and limitations**

42 The present study has several strengths. First, the present study gives a systematic approach to  
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44 investigate the local context in an easy-to-apply way. Second, previous studies have shown that the  
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46 NGT is a valid method in decision-making, based on the expertise of experienced researchers [16-17].  
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48 The NGT made it feasible to reduce a long inventory of contextual factors to a short and concise list  
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50 with the assumedly most relevant ones.

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52 Our study also has some limitations. First, according to the socioecological model, context can be  
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54 divided into various layers: microsystem, mesosystem, exosystem and macrosystem. The present  
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56 study solely focuses on the level of the municipality and not on the individual or cultural level. For  
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58 example, no information is found regarding relevant contextual factors, such as the level of  
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60 coordination between and within services/institutions, or the norms and values within/between  
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62 municipalities [21]. Secondly, the present information was retrieved from three public web-based  
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64 datasets. The correctness of analysis depends on the correctness and accuracy of those datasets (e.g.,  
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66 for many contextual factors the latest update was in 2014-2015, although the intervention study  
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68 started in 2017). Thirdly, regardless of the large amount of information that can be found online, it is  
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70 plausible that a significant amount of relevant information is still missing. For instance, we are aware  
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72 that Knokke-Heist does not have a community center; however, no information is available regarding  
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74 the activities organized by local organizations or other initiatives organized by the municipality that  
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76 could function as an alternative for a community center. Fourthly, several aspects of the 5-step  
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78 approach are based on experts' opinions (e.g., part four and five). This indicates the assumption that  
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80 the D-SCOPE trial can interact with the selected contextual factors. However, further evidence-based  
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82 research is needed.

### 83 **Implications and future research**

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85 New innovations and technologies offer opportunities for contemporary and future scientists. Before  
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87 the existence of the World Wide Web, constructing an inventory of contextual factors in different  
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89 communities would be a considerable and time-consuming challenge. Today, a substantial amount of  
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91 information can be found in online-standardized datasets. This enables future intervention studies to

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3 69 take the local context into account. For instance, the present results can be useful to explain  
4 70 differences in effect of the D-SCOPE intervention in the three municipalities and provide insight  
5 71 regarding contexts that might be supportive for a home visit and those that are not. For instance, older  
6 72 adults in need of extra social contact and participation could not be referred to a community center in  
7 73 Knokke-Heist, while this is possible in Ghent and Thienen, where a community center is available. The  
8 74 lack of a community center in Knokke-Heist could impact how the D-SCOPE intervention affected its  
9 75 outcomes. Based on these insights of the present study, new (theory-driven) hypotheses can be  
10 76 formulated that can be tested, giving a better understanding of mechanisms related to an intervention.  
11 77 Therefore, we would advise researchers to perform an analysis of context before the start of an  
12 78 intervention to avoid post-hoc data-driven analysis in urge to explain the results. In case an  
13 79 intervention study includes many municipalities, a contextual factor can also be used as moderator in  
14 80 the statistical model. Within the D-SCOPE project the availability of a community center could be an  
15 81 independent dummy variable in the statistical analysis: the value 0 = not available in the municipality  
16 82 and the value 1= available in the municipality. Contextual factors can also be changed into an ordinal  
17 83 scale. We illustrate this with the variable 'total resources of the community social security in euros per  
18 84 inhabitant' which can be ordered as 1 = municipality with the lowest resources per capita (Knokke-  
19 85 Heist); 2 = municipality with the mid value (Thienen) and 3 = municipality with the highest resources  
20 86 per capita (Ghent).  
21 87 Because of the proposed five-step approach, future RCTs could meet the criticism of lack of attention  
22 88 to context when evaluating an intervention [1]. This five-step approach can also be used for  
23 89 interventions with other topics (e.g., economic research, criminology) or research for other purposes;  
24 90 for instance, the risk stratification of areas whereby characteristics (e.g., sociodemographic,  
25 91 socioeconomic, care supply) of a village, municipality or city are assessed and compared to macro-level  
26 92 data to determine local (health) needs and challenges [22, 23].  
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## 94 **Conclusion**

95 Some authors argue that certain contexts are supportive for the implementation of an intervention  
96 and some are not, although the role of context is often ignored in RCTs [1]. The present study shows  
97 that it is feasible to perform an analysis of contextual factors that could impact outcomes in a RCT. A  
98 significant amount of information is available online and an easy-to-apply five-step approach can  
99 determine the assumedly most relevant contextual factors. With this five-step approach, future  
100 intervention studies can consider the local context when examining the effect of an intervention and  
101 formulate theory-driven hypotheses in RCTs. This should give us a better understanding of the effects  
102 of an intervention and the mechanisms related to the intervention.  
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3 104 **Author Contributions**  
4

5 105 All authors contributed to the design of the D-SCOPE intervention. The present study within the D-  
6 SCOPE trial was conceived by MVDE, JS, GK, JDL and BS. MVDE developed the inventory and wrote the  
7 106 SCOPE trial was conceived by MVDE, JS, GK, JDL and BS. MVDE developed the inventory and wrote the  
8 first draft of the manuscript. LDD, BF, EDR, DD participated in the NGT and contributed to the data-  
9 107 first draft of the manuscript. LDD, BF, EDR, DD participated in the NGT and contributed to the data-  
10 108 analysis. All authors critically revised the manuscript and reviewed and approved the final manuscript.

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13 109 All authors comply with the conditions of authorship according to the ICMJE

14  
15 110 **Declaration of interests:** none

16  
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19  
20 113 **Data sharing statement:** all data are online available at the websites of the databases

21  
22 114 **Ethics Statement:** The study presents an approach to search for contextual factors and apply this in  
23 the D-SCOPE trial, thereby we only used secondary data. Therefore, an ethical approval is not  
24 115 applicable.  
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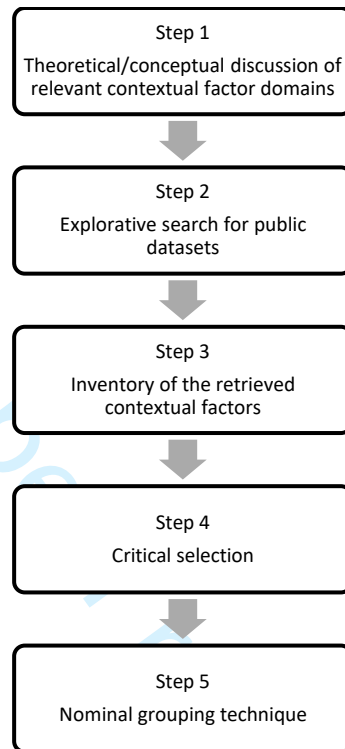
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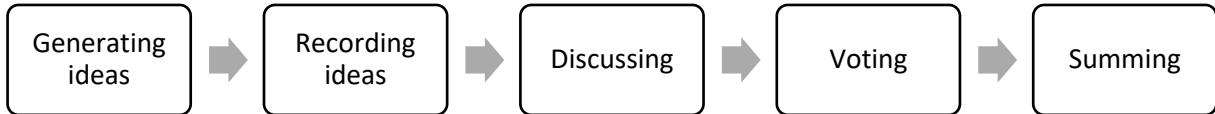
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3 **Figure 1: Flow chart of the five-step approach to determine assumedly the most relevant contextual**  
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**Figure 2: Flow chart Nominal grouping technique**

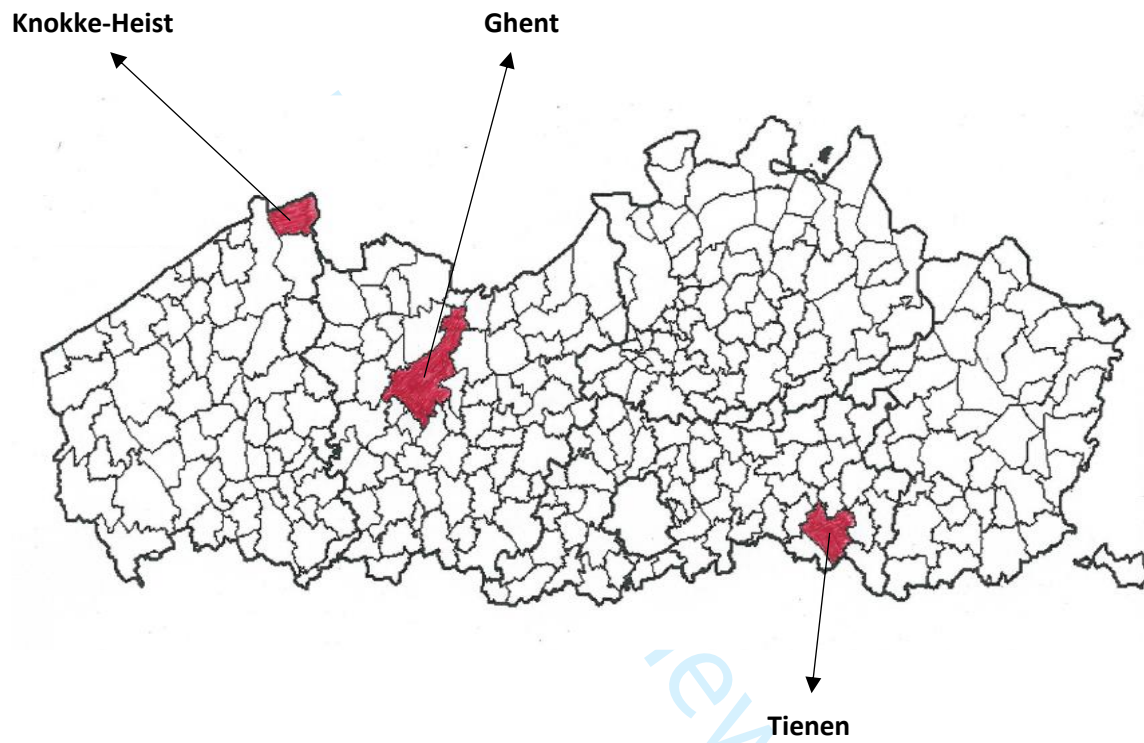


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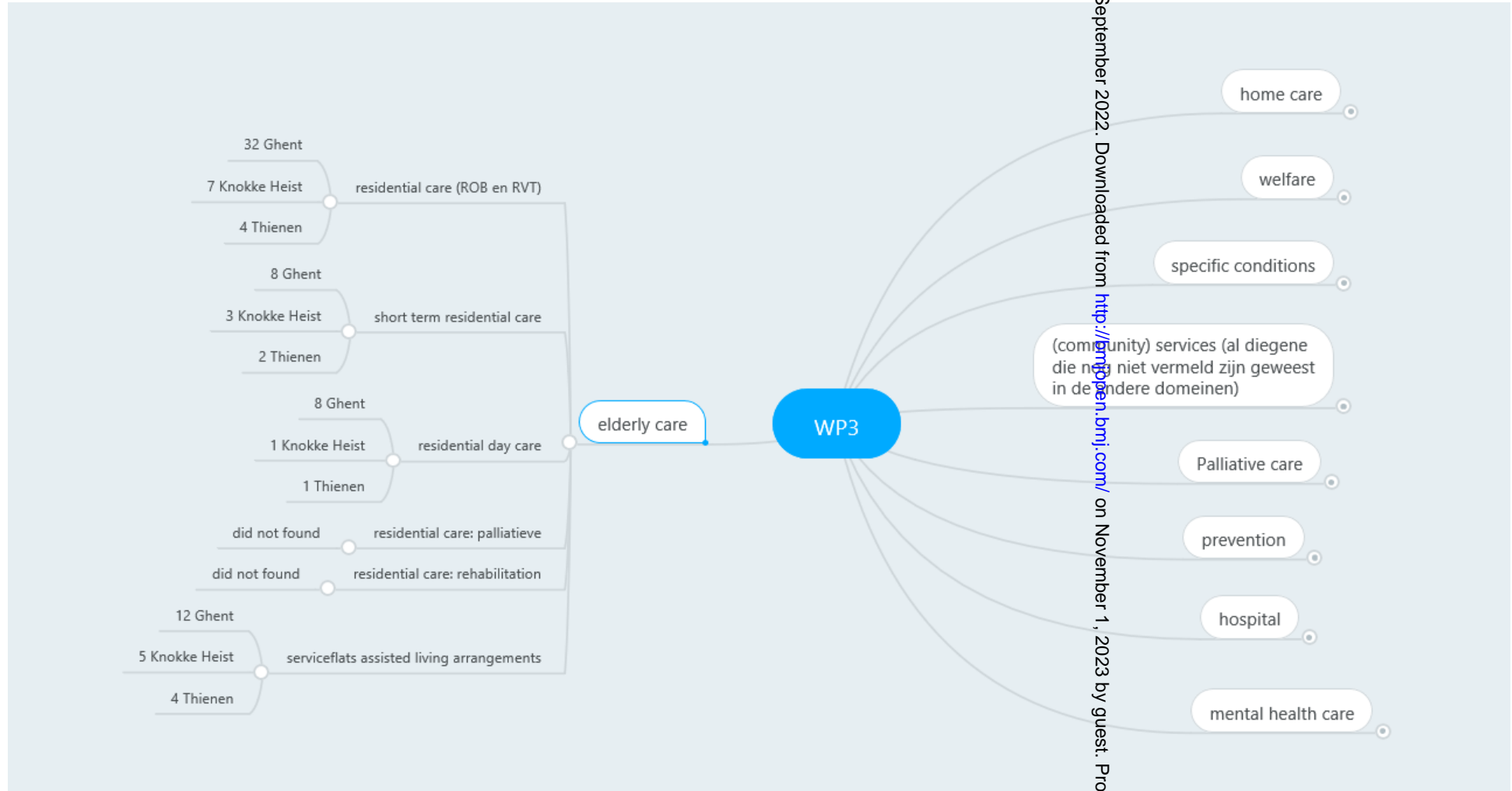


### Supplementary file 1: Map of Flanders (Belgium)

The three municipalities participating in the D-SCOPE programme are Knokke-Heist, Ghent and Tienen.



Supplementary file 2: Mind mapping



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### Supplementary file 3: Databases

**InterMutualistic Agency (IMA):** The IMA collects, manages, and stores the data of the seven Belgian health insurance institutions. Examples of data are percentages of people age 75 or more with chronic illnesses, percentage of people aged 65 or more which make use of day care. The IMA Atlas (website) is an open-source database with health contextual factors. IMA analyzes the data on its own initiative or at the request of other partners. Its aim is to preserve or to improve the performance, the quality, and the accessibility of the Belgian health care system and health insurance.

**Local Statistics:** The Local Statistics website is a joint venture between the Study Center of the Flemish Government, the Agency for Local Government, the Association of Flemish Cities and Municipalities, the Association of Flemish Provinces and the Flemish Community Commission of Brussels. It is a portal site where all types of statistics about local and provincial administrations such as number of people aged 65 and more, total resources of the community social security in euros per inhabitant 2013 (in euro) have been collected. Databases from various policy domains of the Flemish government are brought together.

**Social Map:** The Social Map database collects data from health care organizations (broad interpretation) in a structured database. It contains contact details, qualitative information such as target groups, opening hours, etc. Social Map aims to guide people in need of specific care to the appropriate organization

**Supplementary file 4: Critical selection**

Topic	Indicator	Gent	Knokke-Heist	Tienen	Respondent 1	Respondent 2		
Socio-demographic	Total population 2015	253.266	33.452	33.95	Green	Red		
	Number of people ≥65y and older	42.437	11.163	7.156				
	Percentage of people ≥65y 2015	16,80%	33,40%	21,10%				
	Number of people ≥80y and older	13.978	3.213	2.225				
	Percentage of people ≥80y 2015	5,50%	9,60%	6,60%				
	Growth rate number of people ≥65+ 2005-2014 (2005=100)	101,4	126,8	109,9				
	Dependency ratio (65+/20-64jaar) 2015	27,03%	63,10%	36,21%				
	Population density 2015	1.622	593	473				
Community resources	Total taks revenu municipality per inhabitant (in euro) (2013)	3.352	2.626	1.603	Red	Red		
	Total expenditure municipality per inhabitant (in euro) 2013	3.359	2.505	1.604				
	Debt municipality per inhabitant (in euro) 2013	2.014	1.763	1.653				
	Number of employee municipality per 1000 inhabitants 2013	21	13,1	11,4				
	Total resources of the community social security in euros per inhabitant 2013 (in euro)	304	151	229			Green	Green
	Debt community social security in euros per inhabitant 2013	145	266	548			Red	Red
Socio-economic	Employment rate (20-64) 2013	67,2	68,7	71,1	Red	Yellow		
	Average income per inhabitant (in €) 2012	17.189	23.203	18.248		Green		