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Improving Quality and Safety in Nursing Homes and Home Care: The study protocol of a mixed methods research design to implement a leadership intervention

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3 **Improving Quality and Safety in Nursing Homes and Home Care: The study**
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5 **protocol of a mixed methods research design to implement a leadership**
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7 **intervention**
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8 **ABSTRACT**

9

10 **Introduction**

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12
13 Primary care services such as nursing homes and home care face challenges across different
14 countries as people are living longer, often with chronic conditions. There is a lack of knowledge
15 regarding implementation and impact of quality and safety interventions as most research evidence
16 so far is generated in hospitals. Additionally, there is a lack of effective leadership tools for quality
17 and safety improvement work in primary care.
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24 **Methods and analysis**

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26
27 The aim of the SAFE-LEAD Primary Care project is to develop and evaluate a research-based
28 leadership guide for managers to increase quality and safety competence. The project applies a
29 mixed-methods design and explores the implications of the leadership guide on managers' and staffs'
30 knowledge, attitudes, and practices. Four nursing homes and four home care services from different
31 Norwegian municipalities will participate in the intervention. Surveys, process evaluation (interviews,
32 observations) and document analyses will be conducted to evaluate the implementation and impact
33 of the leadership intervention. A comparative study of Norway and the Netherlands will establish
34 knowledge of the context-dependency of the intervention.
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45 **Ethics and dissemination**

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47 The study is approved by the Norwegian Centre for Research Data (2017/52324 and 54855). The
48 results will be disseminated through scientific articles, two PhD dissertations, an anthology,
49 presentations at national and international conferences, and in social media, newsletters, and in the
50 press. The results will generate knowledge to inform leadership practices in nursing homes and home
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3 care. Moreover, the study will build new theory on leadership interventions and the role of
4
5 contextual factors in nursing homes and home care.

6
7 **KEYWORDS:** quality, safety, primary care, nursing home, home care, leadership, intervention,
8
9 context

10 11 12 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 13
14
15 • The study translates EU research findings from the QUASER project into practice by
16
17 implementing a leadership-focused quality and safety improvement intervention in
18
19 Norwegian nursing homes and home care.
- 20
21
22 • A key strength of the SAFE-LEAD Primary Care study is user involvement in all phases,
23
24 including co-researchers representing patients, next-of-kin, a patient and user
25
26 ombudsman, and managers in primary care.
- 27
28
29 • A mixed-methods design involving a contrasting case study approach enables the
30
31 SAFE-LEAD Primary Care study to explore the role of context when implementing a
32
33 leadership intervention in nursing homes and home care services located in large,
34
35 small, rural and urban municipalities.

36 37 38 **INTRODUCTION**

39 40 41 **Quality and safety challenges in primary care**

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44 Primary care services such as nursing homes and home care face challenges worldwide as people live
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46 longer, often with one or more chronic conditions that should be treated as conservatively as
47
48 possible¹. Most of the research on quality and safety in healthcare is conducted in hospital contexts
49
50 so we know little about other healthcare settings². Numerous quality and safety challenges exist in
51
52 the nursing home and home care contexts. For example, safety in home care is inseparable from
53
54 relationships and interactions between patients, informal caregivers and formal healthcare providers
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3³⁻⁶. In addition, minor mistakes, discontinuity, and multiple care providers with little overview of
4
5 patient status and development may cause cumulative negative effects over time. This cumulative
6
7 effect is especially important when we consider quality and safety at home and in the community¹. In
8
9 this context, the role of organizational structures and processes is under-researched, and there is a
10
11 need for more knowledge on the ways in which organizational and provider factors combine to affect
12
13 quality and safety^{2,7}.
14
15

16 **The role of management and leadership**

17
18 In recent work, Mintzberg⁸ focuses on the importance of leadership in healthcare management, as
19
20 the two have often been separated. Management involvement and a wide range of leadership roles
21
22 and activities are crucial in the development of structures and cultures to improve patient safety and
23
24 achieve sustained quality in healthcare services^{2,9-14}. Although quality and safety improvement work
25
26 in healthcare is predicated on interaction and collaboration among many organizational stakeholders
27
28^{11,15}, the onus is on healthcare managers to commit to improvement efforts and use research-based
29
30 knowledge in planning and improving quality and safety work¹⁶⁻¹⁸. Involving managers in properly
31
32 designed implementation programs has been found to have a positive impact on organizational
33
34 outcomes¹⁹, especially if the programs are comprehensive and systematically integrated into the
35
36 organizational culture²⁰. As such, there is ongoing demand for more and better knowledge about
37
38 quality and safety improvement work focused on the abilities and capacities of managers¹³. Of
39
40 particular concern is strengthening leadership capacity, competence, and quality and safety in
41
42 nursing homes and home care services.
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47 **Understanding the role of context in knowledge translation**

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49 Translating research-based knowledge into practice in healthcare is challenging^{21,22}. One of the key
50
51 challenges for management teams is how to implement evidence-based knowledge to facilitate
52
53 quality and safety improvement at the local service level^{15,23}. Many knowledge translation
54
55 frameworks have been proposed that acknowledge the socially situated nature of knowledge
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3 implementation practices²²⁻²⁴⁻²⁶. Nevertheless, the literature says little about the influence of context
4
5 on successful quality and safety implementation interventions in healthcare^{23 27-30}. Context can refer
6
7 to both the inner (internal) and outer (external) settings of an organization. Internal organizational
8
9 factors include structural characteristics (e.g., location and size); the local workings of teams and
10
11 leadership; and the organizational culture and implementation climate. Among the external factors
12
13 are applicable laws, regulatory requirements, external policies and incentives, and funding
14
15 structures²⁹. Differences in internal and external organizational contexts are thought to be
16
17 responsible for some of the variability seen in the implementation of quality and safety improvement
18
19 efforts in diverse local practice settings^{28 29}. However, there are few if any studies of the role of
20
21 contextual factors in leadership interventions in primary care settings.
22

23 24 **Organization and quality and safety status of primary care in Norway**

25
26
27 Although the organization and responsibilities of healthcare systems can differ, the primary care
28
29 setting is an important arena for the provision of health and social care services in Norway as in many
30
31 other countries. In Norway, the delivery of primary care services is the responsibility of the
32
33 municipalities, which provide most of the country's home care and nursing home services. The
34
35 Norwegian municipalities are by law required to work to improve healthcare quality and safety, and
36
37 managers at all service levels are responsible for the planning, implementation, evaluation and
38
39 systematic improvement of service quality and safety.
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42
43 However, as noted in a recent government white paper on Norwegian primary care services, quality
44
45 and safety efforts in municipal health services to date have been insufficient³¹. Inspections made by
46
47 the Norwegian Board of Health Supervision have repeatedly found inadequate quality assurance and
48
49 control measures across primary care organizations. While quality improvement and safety efforts
50
51 should be a top priority of municipal management teams, quality and safety work is often poorly
52
53 rooted in management, and in some places not considered a management task at all³². Where quality
54
55 and safety improvement work has been undertaken, there have been challenges in translating
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3 knowledge into practice³¹. Such reports have led to the conclusion that there is a serious lack of basic
4
5 leadership competencies related to quality and safety improvement work in Norwegian primary care
6
7 services. The latter constitutes the major rationale for conducting the SAFE-LEAD Primary Care study.
8

9 10 **Aims and research questions**

11
12 The SAFE-LEAD Primary Care study is translating research findings from the EU FP7 funded project
13
14 QUASER into practice in Norway by implementing a leadership-focused quality and safety
15
16 improvement intervention in the primary care setting. The intervention is built around the
17
18 implementation of a quality and safety improvement tool, which is a leadership guide for managers
19
20 in nursing homes and home care. The leadership guide is based on the results from the QUASER
21
22 study³³ where the consortium, including SAFE-LEAD partners, developed the *QUASER Hospital Guide -*
23
24 *A research-based tool to reflect on and develop your quality improvement strategies*³⁴. The QUASER
25
26 Hospital Guide defines quality as care that is clinically effective, safe, and patient-centred. The guide
27
28 is structured around eight quality challenges (structure, culture, leadership, politics, education,
29
30 emotions, physical and technical issues, external demands). A short series of questions will stimulate
31
32 reflection, accompanied by a decision-aid menu of potential options, with empirical examples of
33
34 possible quality and safety improvement solutions across the macro, meso, and micro system levels.
35
36 The guide is designed to facilitate patient safety and quality improvement in clinical practice and
37
38 service delivery, by providing a systematic means for managers to pinpoint the strengths and
39
40 weaknesses of their improvement strategies and reflect on what the tailored measures needed in
41
42 their institution and context.
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47 The SAFE-LEAD Primary Care study will investigate how and to what extent different contextual
48
49 factors influence the implementation process and the effectiveness of such a research-based guide in
50
51 a variety of nursing homes and home care services. The aim of the study is to build leadership
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53 competence and guide primary care managers in their efforts to advance and improve vital quality
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3 and safety strategies, attitudes and practices in their organizations. The specific objectives of the
4
5 SAFE-LEAD Primary Care study are to:

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8 a) Investigate the influence of context on the implementation of a research-based quality and
9
10 safety leadership intervention in primary care
11
12 b) Test the effectiveness of the leadership intervention on changes in managers' and healthcare
13
14 professionals' knowledge, attitudes and practices relating to quality and safety in primary care
15
16 c) Develop theory to guide implementation of future leadership interventions designed to improve
17
18 the quality and safety in primary care
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20
21 The following research questions will guide the SAFE-LEAD Primary Care study:

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23
24 1. What are the key contextual factors that affect quality and safety improvement work in the
25
26 Norwegian primary care setting?
27
28 2. How can the SAFE-LEAD Primary Care intervention best be designed to implement use of a
29
30 leadership guide in primary care?
31
32 3. Which contextual factors, including leadership practices and processes influence successful
33
34 implementation and use of a leadership guide in primary care?
35
36 4. How can patient and next-of-kin involvement be integrated into use of a leadership guide and
37
38 the overall SAFE-LEAD Primary Care intervention?
39
40 5. What is the impact of the SAFE-LEAD Primary Care intervention on managers' and staffs' quality
41
42 and safety knowledge, attitudes, and practice?
43
44 6. What are the implications of the SAFE-LEAD Primary Care research findings on the development
45
46 of theoretical frameworks for organizational context, leadership processes, and quality and
47
48 safety improvement efforts in primary care settings?
49
50 7. What are the similarities and differences in contextual factors determining successful
51
52 implementation of research-based quality and safety improvement tools in Norway and the
53
54 Netherlands?
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3 8. How and to what extent do the identified key contextual factors explain implementation, uptake,
4 and impact of the SAFE-LEAD Primary Care intervention across nursing homes and home care
5 services?
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9 10 **METHODOLOGY**

11 12 **Design**

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14
15 The SAFE-LEAD Primary Care study (2016-2021) applies a convergent parallel mixed-methods
16 design³⁵. We will collect both quantitative and qualitative data in parallel, analyse them separately
17 and compare results subsequently³⁵.
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22 23 **Setting**

24
25 The main study setting is nursing homes and home care in the Norwegian primary care system. In
26 addition, a small-scale study will take place in a nursing home and a home care institution in the
27 Netherlands.
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30
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32 33 **Study sample and recruitment**

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35 Four nursing homes and four home care services from different Norwegian municipalities will be
36 recruited to participate in the SAFE-LEAD Primary Care intervention. To understand the role of
37 context, the sampling strategy is based on a contrasting case approach³⁶, with selection criteria
38 focusing on diversity in size, geography, and variation between urban and rural services. A similar
39 small-scale study of one nursing home and one home care service will be conducted in the Dutch
40 healthcare setting, allowing for comparison of two countries with different national healthcare and
41 regulatory systems. The recruitment of Norwegian institutions will be conducted in collaboration
42 with two Centres for Development of Institutional and Home Care Services (Rogaland County, Sogn
43 and Fjordane County) and the municipality of Songdalen in Vest-Agder County. The Dutch research
44 team will recruit the institutions in the Netherlands.
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Data collection methods and sources

The study is structured around five work packages indicating distinct phases of the project. In the following, we describe the phases, data collection and sources.

Phase 1: Guide development, pilot test, and contextual mapping tool (WP1)

In phase 1, we will develop the quality and safety improvement tool – the SAFE-LEAD guide – to be used in the SAFE-LEAD Primary Care intervention. This includes translation and adaptation of the QUASER Hospital Guide into Norwegian in a process involving the research team in several iterations with professional translation services, co-researchers, future users, and patient and next-of-kin representatives. The original QUASER-guide is based on empirical findings from the hospital setting and the SAFE-LEAD Primary Care project will develop a version adapted to the Norwegian primary care setting focusing on nursing homes and home care. This development process will consist of internal workshops with the multidisciplinary research team with competence in nursing, homecare, nursing homes, quality and safety, leadership, health promotion, and human factors. There will also be workshops with co-researchers in the SAFE-LEAD Primary Care partner consortium ensuring sound user involvement with perspectives from patient representatives, next-of-kin representatives, a patient and user ombudsman, and perspectives from future users of the guide (managers in primary care). To ensure that the guide fits the primary care context, we will conduct 3-4 focus group interviews to collect input from managers in nursing homes and home care services who will have read the guide beforehand. Finally, the guide will be tested for fit and validity in one nursing home and one home care service with senior healthcare managers and their teams as part of the pilot test of the intervention (described in phase 2).

To facilitate implementation and use of the guide, we will also offer a web-based version. The web version will have the same content as the paper version and will be published and available for all Norwegian primary care institutions on a SAFE-LEAD Primary Care website after completion of the project in 2021.

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3 To assess the influence of contextual factors, we will develop a mapping tool for use in the
4 implementation and evaluation phase of the project. This will be inspired by 1) Damschroder et al.'s
5
6 ²⁵ Consolidated Framework for Implementation Research (CFIR) and McDonald's²⁹ framework for
7
8 considering context in quality and safety improvement interventions, 2) additional literature
9
10 searches, and 3) a qualitative study with 10-12 nursing home and home care managers in a variety of
11
12 Norwegian municipalities (large, small, rural, urban). In the interviews, we will map the contextual
13
14 factors of relevance for managers' work on quality and safety in primary care. The interview guide
15
16 includes open questions regarding which factors managers perceive as important for their work with
17
18 quality and safety, and topics such as external factors, economy, and structure. The tool will consider
19
20 factors such as type of healthcare service (nursing home or homecare), funding, geographical
21
22 location, organization size, workload, and any ongoing national/regional/organizational change
23
24 processes.
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27 28 Phase 2: Intervention design, pilot testing, and recruitment (WP2) 29

30
31 The Medical Research Council's guidance on developing, testing and evaluating complex
32
33 interventions to improve healthcare^{37 38} will be used to design the intervention. This framework
34
35 views healthcare interventions as flexible, non-linear processes, giving equal attention to all process
36
37 phases (development, testing, evaluation, wider application). Furthermore, it stresses the
38
39 importance of context in implementation and allows an intervention to be adapted to its setting, to
40
41 better ensure its success in practice^{37 38}. The application of an organizational perspective has been
42
43 suggested as an aid to understanding the contextual factors and processes that may enable or
44
45 impede knowledge implementation interventions in healthcare settings^{29 39}. As the SAFE-LEAD
46
47 Primary Care study is concerned with implementation in practice, the Organizing for Quality (OQ)
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49 framework^{11 40} will be used as a theoretical foundation in the intervention design, alongside the
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51 Consolidated Framework for Implementation Research (CFIR)²⁵. Both frameworks advocate a multi-
52
53 level contextual perspective on the implementation and evaluation of interventions.
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The SAFE-LEAD Primary Care intervention

The SAFE-LEAD Primary Care intervention will be conducted in two stages over a period of one year³⁷.

Stage 1 is a training component involving action learning workshops in which primary care managers and their teams will be able to apply the guide and conduct a self-diagnosis of their current quality and safety work. A team of experienced researchers will facilitate reflexive group discussions among the teams, which will take place in four group sessions (2-3 hours each) in all participating institutions over a six-month period. It is proposed that each group will consist of an extended management team (director of health and care services in municipality, nursing home director/director of homecare services, department managers, head nurses, nursing home physicians, and patient or next-of-kin representatives). These sessions will:

1. Introduce the guide to the participating institutions. This includes rationale, concepts, web-tool, and procedure for an internal management process for use of the guide within the organization.
2. Provide guidance for integrating patient and next of kin experiences in quality and safety improvement work.
3. Establish strategies to address the diagnosed quality and safety challenges.

In Stage 2 of the intervention, a sample of two nursing homes and two home care services (from the total sample of eight institutions) will receive a more comprehensive intervention component consisting of a close collaboration with the researchers. In addition to the training component described in Stage 1, the institutions in stage 2 will receive three site visits by researchers (1-3 days) per institution over a period of 12 months (Stage 1 + Stage 2=12 months). Activities during site visits will include:

1. A workshop to support existing and new learning arenas in quality and safety improvement work (1 day).
2. Observation of and feedback on quality and safety leadership strategy and practices (3 days).

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3 3. A workshop to support the integration of patient and next-of-kin experiences in
4
5 improvement work (1 day).
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8 A pilot test of the Stage 1 intervention will be conducted in one nursing home and one home care
9
10 services setting over a three-month period to test the chosen intervention contents, pedagogical
11
12 approaches, and the functionality of the guide developed in Phase 1. We will evaluate the pilot
13
14 intervention components by means of a qualitative process evaluation^{37 38 41} involving observation in
15
16 the workshops and semi-structured interviews with pilot intervention participants (15-20). The pilot
17
18 will not test the outcome measures. The intervention will be tailored based on the pilot results.
19

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21 Phase 3: Testing and evaluating the SAFE-LEAD Primary Care intervention (WP 3)
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24 In Phase 3, we will implement the intervention Stage 1 and 2. Before and during the implementation
25
26 process, we will map contextual factors in all participating institutions by using the context mapping
27
28 tool developed in Phase 1.
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31 The SAFE-LEAD Primary Care intervention is centred on the testing in practice of a research-based
32
33 quality and safety improvement guide for managers. The Knowledge to Action framework²² will be
34
35 used to guide this part of the intervention. This approach proposes that the translation into practice
36
37 of a research-based guide requires an organisation to identify the problems it needs to solve; adapt
38
39 the guide to its own settings and contexts; assess and address barriers to its use; implement the
40
41 intervention; monitor the implementation and evaluate the outcomes⁴². The contents and
42
43 procedures involved in this phase of the SAFE-LEAD Primary Care intervention will be designed and
44
45 developed in close collaboration with the participating primary care representatives in the research
46
47 team, based on a reflexive, dialogue-based group technique.
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49
50 The evaluation of the study entails both an in-depth qualitative work to understand the process of
51
52 implementing the quality and safety improvement guide in practice; how the participating primary
53
54 care institutions use the guide; and a quantitative measurement of the impact of the guide on quality
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56 and safety improvement knowledge and practices in these institutions.
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3 Although the SAFE LEAD Primary Care intervention is a leadership intervention designed to address
4 leadership issues, knowledge must be disseminated and applied at the clinical level (e.g., nurses and
5 doctors) for the implementation to be effective. In the evaluation of Stage 1, we will assess the
6 relationship between using the guide and changes in staffs' and managers' quality and safety
7 knowledge, attitudes and practices in all eight participating institutions. We will measure this
8 relationship by using a knowledge, attitude and practice (KAP) survey. We will conduct a literature
9 review to identify and select measurement scales for the survey questionnaire. Managers and staff
10 in all participating institutions will be invited to respond to the baseline survey questionnaire before
11 the intervention starts. A second survey questionnaire will be administered to the study participants
12 after the Stage 1 intervention (after six months). The rationale is to measure changes in quality and
13 safety knowledge, attitudes and practices following the intervention program Stage 1.
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16
17 The purpose of intervention Stage 2 is to establish learning arenas, structures and processes to
18 support leaders' self-diagnosis of their quality and safety work, and strengthen their capacity to
19 conduct future improvement without researcher involvement. To evaluate the intervention Stage 2,
20 we will conduct a process evaluation^{38 41}. The process evaluation will require active researcher
21 involvement in the intervention workshops. Data collection to evaluate the intervention processes in
22 each of the four institutions (Stage 2) will comprise semi-structured interviews before and after the
23 intervention period (over 12 months) with managers (approximately 5-10 x 2 depending on
24 institution size) and staff (approximately 8-10 x 2 depending on institution size), observation of the
25 intervention workshops and daily practice situations in the selected institutions (40-50 hours), as well
26 as document analysis of strategies, plans, and regulatory inspection reports. During the intervention
27 period, we will also conduct short follow-up conversations with managers participating in the
28 intervention to collect information for use in the observation and feedback sessions. This implies a
29 total of approximately 160 semi-structured interviews and 150-200 hours of observation. Interview
30 guides and observation guides have been developed for managers and healthcare professionals.
31 These guides are based on Bate et al.¹¹ and cover quality and safety challenges in terms of culture,
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3 structure, enthusiasm, education, politics, external demands, physical and technical aspects, use of
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5 diverse tools in improvement work, and changes to these factors over time at the managerial and
6
7 healthcare professional level. The study will apply NVivo to structure, categorize and analyse the
8
9 qualitative data according to categories relevant for quality and safety improvement challenges¹¹.

10
11 Data will be analysed within cases before conducting the cross-case comparison⁴³.

12
13
14 Across phase 1-3: tracer project on quality improvement in home care (WP4)

15
16 To arrive at an in-depth understanding of the role of context and leadership in daily quality
17
18 improvement work, we will include a tracer quality improvement project as part of the data
19
20 collection³³. The tracer project will be studied longitudinally over the entire project period with a
21
22 combination of qualitative interviews, document analysis, observation, and shadowing of staff. In the
23
24 tracer project, we will evaluate an improvement project titled “ABCDE – systematic observation and
25
26 communication in community health care”. The improvement project aims at 1) developing a
27
28 tailored educational program designed to improve healthcare professionals’ competencies and skills
29
30 in recognizing and responding to deteriorating frail patients, and 2) implementing new work routines
31
32 in the home care organizations to strengthen healthcare professionals’ understanding and clinical
33
34 judgment of deteriorating patients. The tracer project is identified with the project partners and is
35
36 initiated by one of the partner municipalities. The SAFE-LEAD Primary Care study will examine
37
38 improvement processes in real time as exemplars of how quality improvement is implemented. The
39
40 tracer project will enable lessons learnt, and contribute to understanding how managers are
41
42 improving the professional observational skills of their staff in the home care context.
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47 Phase 4: Mixed-methods synthesis, cross-country comparison, theory development (WP5)

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49 The SAFE-LEAD Primary Care study is an opportunity to understand the meaning and impact of
50
51 contextual factors by analysing the influence of the quality and safety improvement guide
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53 implementation via three data sets: 1) a quantitative survey of outcome measures (knowledge,
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55 attitudes, practice) across a sample of eight institutions, 2) a context mapping of all participating
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3 institutions, and 3) a qualitative multiple case study with a smaller sample of four institutions
4 providing rich information on leadership processes and practices, a small-scale implementation case
5 study in the Netherlands, and a tracer quality improvement project. In this sense, the study pays
6 closer and more explicit attention to multiple contextual factors^{44 45}, and the way in which they affect
7 the success and sustainability of implementing quality and safety improvement tools.
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14 The different data sets will be collected in parallel and analysed separately³⁵. In Phase 4 of the study
15 we will synthesise the results from the qualitative, quantitative, and context data sets by using a
16 procedure called "joint display of data"³⁵. The researchers will jointly display all forms of data (e.g., in
17 tables or in NVivo) responding to similar concepts and research questions. The analysis of the total
18 amount of data in the Norwegian part of the study will compare the results from the concepts
19 measured in the KAP survey, and what is mapped by qualitative process evaluation methods, and the
20 findings from the tracer project. The outcomes of the analyses will be used to develop theoretical
21 frameworks and conceptual models of the influence of context and leadership on quality and safety
22 improvement work in primary care settings.
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33 The Norwegian results will then be compared with Dutch results from a similar small-scale research
34 project. The Dutch cases are used to contrast the nursing homes and home care in Norway, as the
35 Dutch healthcare system frequently uses a greater range of improvement tools as part of managing
36 quality and safety than the Norwegian. The cross-country analysis will compare and contrast
37 managers' practice and competence, and whether staff members make changes in their work
38 practice to improve quality and safety of service provision. The comparison will build on a contrasting
39 case approach⁴³ based on the differences between the organisation of quality and safety work in
40 healthcare systems in the two countries. Building on the approach taken in the QUASER study³³, a
41 multilevel perspective will be used, considering important macro-level contextual factors (national
42 healthcare system), in addition to the factors identified at the meso and micro levels in the case
43 studies. We will look at effects of different contextual factors such as funding frameworks,
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3 regulation, prioritisation, organisation, and competence level. National differences will be analysed
4
5 to better understand the effect of macro-level healthcare system factors on the success of quality
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7 improvement implementation processes.
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9 10 **ETHICS AND DISSEMINATION**

11 12 **Ethical reflections**

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14
15 The SAFE-LEAD Primary Care leadership-focused intervention targets a potential knowledge gap
16
17 among managers and supports their work on quality and safety improvement. The risk of negative
18
19 effects on patient outcomes is thus minimal. The potential of not having a positive effect of the
20
21 intervention on managers' leadership competence is present, but the risk of negative patient
22
23 outcome due to this is limited. The patient and next-of-kin perspectives are key throughout the SAFE-
24
25 LEAD Primary Care study. Patients and next-of-kin representatives participated in the project
26
27 development and will collaborated with the project team as co-researchers throughout the project
28
29 period. Different measures are involved in the quality and safety improvement guide itself
30
31 (strategies, measures) and in the intervention components (workshops on use of patient
32
33 experiences) to improve managers' abilities to involve patient and next of kin in improvement work.
34
35

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37 The SAFE-LEAD Primary Care study is approved by the Norwegian Centre for Research Data
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39 (2017/52324 and 54855), and exempted from ethical approval from Regional Ethical Committee
40
41 because no health information will be collected. The Norwegian approval also includes approval for
42
43 data collection in the Netherlands. The Dutch ethical approval system does not require ethical
44
45 approval for research projects not involving patient data, as in the SAFE-LEAD Primary Care. All
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47 participants will sign informed consent and will be recruited on a voluntary basis. No patient records
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49 or other patient data will be collected.
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51 52 **Dissemination**

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The SAFE-LEAD Primary Care partners have agreed upon publication guidelines, a publication strategy, and a publication plan. The publication strategy consists of dissemination in scientific peer-reviewed journals, books and presentations at academic conferences. Moreover, there is a strategy to ensure dissemination in popular science forums and in social media. The project has established a SAFE-LEAD web page, a SAFE-LEAD Facebook account, newsletters, and posters. The project has an international expert advisory board that will be invited annually to give input to the study and contribute to the sharing of results.

The publication plan will evolve over time but includes the following planned scientific dissemination activities:

- Two PhD theses (authors Terese Johannessen and Torunn Strømme).
- 18-20 scientific articles in a peer-reviewed special issue and in different peer-reviewed journals.
- A book on Quality and Safety in Primary Care involving international contributions.
- Local seminars at the study sites (including user groups).
- Norway-Netherland seminar in 2020 to present final project results. Open seminar with target group healthcare managers, inspection authority, researchers, user groups, professional associations, governmental bodies, etc.
- Special sessions at the 5th and 6th Nordic Conference on Research in Patient Safety and Quality in Healthcare.
- Presentations at regional, national and international conferences.
- Popular science presentations in national media and healthcare magazines.

Ten primary publications are planned (see Table 1):

Table 1. Planned primary publications from the SAFE-LEAD Primary Care study

Articles	Planned Scientific Article	Main data source
Article 1	Improving Quality and Safety in Nursing Homes	Literature

	and Home Care: The study protocol of a mixed methods research design to implement a leadership intervention	Policy documents Scientific methods
Article 2	Mapping of contextual factors in primary care - a mixed methods design	Literature review Context mapping Semi-structured interviews
Article 3	Designing an intervention for improving leadership of quality and safety in nursing homes and home care.	Semi-structured interviews Partner workshops
Article 4	Literature review of measurement scales of relevance for mapping quality and safety knowledge, attitudes, and practice in primary care.	Literature review
Article 5	Understanding the role of a leadership intervention on quality and safety leadership processes	Process evaluation including semi-structured interviews, focus group interviews, observation
Article 6	The impact of a leadership intervention on quality and safety knowledge, attitudes and practice in primary care.	Quantitative data from KAP survey
Article 7	Implementation of a quality and safety improvement guide and effects on quality and safety work in a nursing home context.	Mix: KAP survey Process evaluation Context mapping
Article 8	Implementation of a quality and safety	Mix:

	improvement guide and effects on quality and safety work in a home care context.	KAP survey Process evaluation Context mapping
Article 9	The meaning of context: Comparing the implementation of a quality and safety improvement guide in the nursing home and home care context	Mix: KAP survey Process evaluation Context mapping
Article 10	Cross country comparison of working on quality and safety in Norwegian and Dutch primary care services.	Mix: KAP survey Process evaluation Context mapping

AUTHORS' CONTRIBUTIONS

SW and KAa applied for funding of the SAFE-LEAD Primary Care study to the RCN, planned the study design and study protocol, and contributed to the development of the data collection tools. SW and ER drafted the manuscript, with substantial input from KAa, and revised it based on comments from all co-authors. ER contributed to the study design, development of data collection tools, and was responsible for the application for approval of the study to the Norwegian Centre for Research Data. Authors TS, TJ and MS contributed to the study design and development of data collection tools, and commented on the draft. Authors HvB and RB contributed to the study design and development of the data collection tools, commented on the draft, and are responsible for the Dutch part of the study. Authors IAa, BU, EHR, LHT, and ATSP contributed to the study design and have commented on the draft. All authors have approved the final version of the manuscript.

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6

7 **COMPETING INTEREST**

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10 The authors declare there are no conflict of interest.
11

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13
14
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22
23 LEAD project who have provided input to the study design and development.
24

25
26
27 The leadership guide applied in the SAFE-LEAD study is based on the results from the study *Quality*
28
29 *and Safety in European Union Hospitals: A Research-based Guide for Implementing Best Practice and*
30
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BMJ Open

Improving Quality and Safety in Nursing Homes and Home Care: The study protocol of a mixed methods research design to implement a leadership intervention

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Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health services research
Keywords:	quality, patient safety, PRIMARY CARE, leadership, intervention, context

SCHOLARONE™
Manuscripts

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3 **Improving Quality and Safety in Nursing Homes and Home Care: The study**
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5 **protocol of a mixed methods research design to implement a leadership**
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23
24
25 Word count, excluding references: 4431

26 27 28 29 30 31 32 33 34 35 **ABSTRACT**

36 37 38 **Introduction**

39
40
41 Nursing homes and home care face challenges across different countries as people are living longer,
42 often with chronic conditions. There is a lack of knowledge regarding implementation and impact of
43 quality and safety interventions as most research evidence so far is generated in hospitals.
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45 Additionally, there is a lack of effective leadership tools for quality and safety improvement work in
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47 this context.
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51 52 **Methods and analysis**

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3 The aim of the 'Improving Quality and Safety in Primary Care – Implementing a Leadership
4 Intervention in Nursing Homes and Homecare' (SAFE-LEAD) study is to develop and evaluate a
5 research-based leadership guide for managers to increase quality and safety competence. The
6 project applies a mixed-methods design and explores the implications of the leadership guide on
7 managers' and staffs' knowledge, attitudes, and practices. Four nursing homes and four home care
8 services from different Norwegian municipalities will participate in the intervention. Surveys, process
9 evaluation (interviews, observations) and document analyses will be conducted to evaluate the
10 implementation and impact of the leadership intervention. A comparative study of Norway and the
11 Netherlands will establish knowledge of the context-dependency of the intervention.

22 **Ethics and dissemination**

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25 The study is approved by the Norwegian Centre for Research Data (2017/52324 and 54855). The
26 results will be disseminated through scientific articles, two PhD dissertations, an anthology,
27 presentations at national and international conferences, and in social media, newsletters, and in the
28 press. The results will generate knowledge to inform leadership practices in nursing homes and home
29 care. Moreover, the study will build new theory on leadership interventions and the role of
30 contextual factors in nursing homes and home care.

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38 **KEYWORDS:** quality, safety, primary care, nursing home, home care, leadership, intervention,
39 context
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43 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

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46 • The study translates European Union research findings into practice by implementing
47 a leadership-focused quality and safety improvement intervention in Norwegian
48 nursing homes (4) and home care (4).
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- A key strength of the SAFE-LEAD study is user involvement in all phases, including co-researchers representing patients, next-of-kin, a patient and user ombudsman, and managers in nursing homes and home care.
- A mixed-methods design involving a contrasting case study approach enables the SAFE-LEAD study to explore the role of context when implementing a leadership intervention in nursing homes and home care services located in large, small, rural and urban municipalities.
- Process evaluation over 12 months will be limited to 4 out of 8 recruited institutions in the SAFE-LEAD intervention giving few possibilities for generalizing results.
- Despite a detailed adaptive process with an extensive level of user involvement, building on a leadership guide initially developed for the hospital context might disregard information vital for the nursing home and home care services context.

INTRODUCTION

Quality and safety challenges

Nursing homes and home care face challenges worldwide as people live longer, often with one or more chronic conditions that should be treated as conservatively as possible¹. Most of the research on quality and safety in healthcare is conducted in hospital contexts so we know little about other healthcare settings². Numerous quality and safety challenges exist in the nursing home and home care contexts. For example, safety in home care is inseparable from relationships and interactions between patients, informal caregivers and formal healthcare providers³⁻⁶. In addition, minor mistakes, discontinuity, and multiple care providers with little overview of patient status and development may cause cumulative negative effects over time. This cumulative effect is especially important when we consider quality and safety at home and in the community¹. In this context, the role of organizational structures and processes is under-researched, and there is a need for more

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3 knowledge on the ways in which organizational and provider factors combine to affect quality and
4
5 safety^{2,7}.

6 7 8 **The role of management and leadership**

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10 In recent work, Mintzberg⁸ focuses on the importance of leadership in healthcare management, as
11
12 the two have often been separated. Management involvement and a wide range of leadership roles
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14 and activities are crucial in the development of structures and cultures to improve patient safety and
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16 achieve sustained quality in healthcare services^{2,9-14}. Although quality and safety improvement work
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18 in healthcare is predicated on interaction and collaboration among many organizational stakeholders
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20^{11,15}, the onus is on healthcare managers to commit to improvement efforts and use research-based
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22 knowledge in planning and improving quality and safety work¹⁶⁻¹⁸. Involving managers in properly
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24 designed implementation programs has been found to have a positive impact on organizational
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26 outcomes¹⁹, especially if the programs are comprehensive and systematically integrated into the
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28 organizational culture²⁰. As such, there is ongoing demand for more and better knowledge about
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30 quality and safety improvement work focused on the abilities and capacities of managers¹³. Of
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32 particular concern is strengthening leadership capacity, competence, and quality and safety in
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34 nursing homes and home care services.
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38 39 **Understanding the role of context in knowledge translation**

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41 Translating research-based knowledge into practice in healthcare is challenging^{21,22}. One of the key
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43 challenges for management teams is how to implement evidence-based knowledge to facilitate
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45 quality and safety improvement at the local service level^{15,23}. Many knowledge translation
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47 frameworks have been proposed that acknowledge the socially situated nature of knowledge
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49 implementation practices^{22,24-26}. Nevertheless, the literature says little about the influence of context
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51 on successful quality and safety implementation interventions in healthcare^{23,27-30}. Context can refer
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53 to both the inner (internal) and outer (external) settings of an organization. Internal organizational
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55 factors include structural characteristics (e.g., location and size); the local workings of teams and
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3 leadership; and the organizational culture and implementation climate. Among the external factors
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5 are applicable laws, regulatory requirements, external policies and incentives, and funding
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7 structures²⁹. Differences in internal and external organizational contexts are thought to be
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9 responsible for some of the variability seen in the implementation of quality and safety improvement
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11 efforts in diverse local practice settings^{28 29}. However, there are few if any studies of the role of
12
13 contextual factors in leadership interventions in nursing homes and home care.
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16 **Organization and quality and safety status of primary care in Norway**

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18 Although the organization and responsibilities of healthcare systems can differ, the primary care
19
20 setting is an important arena for the provision of health and social care services in Norway as in many
21
22 other countries. In Norway, the delivery of primary care services is the responsibility of the
23
24 municipalities, which provide most of the country's home care and nursing home services, which is
25
26 within the scope of our study. The Norwegian municipalities are by law required to work to improve
27
28 healthcare quality and safety, and managers at all service levels are responsible for the planning,
29
30 implementation, evaluation and systematic improvement of service quality and safety.
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35 However, as noted in a recent government white paper on Norwegian primary care services, quality
36
37 and safety efforts in municipal health services to date have been insufficient³¹. Inspections made by
38
39 the Norwegian Board of Health Supervision have repeatedly found inadequate quality assurance and
40
41 control measures across primary care organizations. While quality improvement and safety efforts
42
43 should be a top priority of municipal management teams, quality and safety work is often poorly
44
45 rooted in management, and in some places not considered a management task at all³². Where quality
46
47 and safety improvement work has been undertaken, there have been challenges in translating
48
49 knowledge into practice³¹. Such reports have led to the conclusion that there is a serious lack of basic
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51 leadership competencies related to quality and safety improvement work in Norwegian primary care
52
53 services. The latter constitutes the major rationale for conducting our study.
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56 **Aims and research questions**

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3 The 'Improving Quality and Safety in Primary Care – Implementing a Leadership Intervention in
4 Nursing Homes and Homecare' (SAFE-LEAD) study is translating research findings from the European
5 Union 7th Framework Programme (EU FP7) funded project 'Quality and Safety in Europe by Research'
6 (QUASER) into practice in Norway by implementing a leadership-focused quality and safety
7 improvement intervention in the nursing homes and home care settings. The intervention is built
8 around the implementation of a quality and safety improvement tool, which is a leadership guide for
9 managers in nursing homes and home care. The leadership guide is based on the results from the
10 QUASER study³³ where the consortium, including SAFE-LEAD partners, developed the *QUASER*
11 *Hospital Guide - A research-based tool to reflect on and develop your quality improvement*
12 *strategies*³⁴. The QUASER Hospital Guide defines quality as care that is clinically effective, safe, and
13 patient-centred. The guide is structured around eight quality challenges (structure, culture,
14 leadership, politics, education, emotions, physical and technical issues, external demands). A short
15 series of questions will stimulate reflection, accompanied by a decision-aid menu of potential
16 options, with empirical examples of possible quality and safety improvement solutions across the
17 macro, meso, and micro system levels. The guide is designed to facilitate patient safety and quality
18 improvement in clinical practice and service delivery, by providing a systematic means for managers
19 to pinpoint the strengths and weaknesses of their improvement strategies and reflect on what the
20 tailored measures needed in their institution and context.

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41 The SAFE-LEAD study will investigate how and to what extent different contextual factors influence
42 the implementation process and the effectiveness of such a research-based guide in a variety of
43 nursing homes and home care services. The aim of the study is to build leadership competence and
44 guide managers in their efforts to advance and improve vital quality and safety strategies, attitudes
45 and practices in their organizations. The specific objectives of the SAFE-LEAD study are to:

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52 a) Investigate the influence of context on the implementation of a research-based quality and
53 safety leadership intervention in nursing homes and home care.
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3 b) Test the effectiveness of the leadership intervention on changes in managers' and healthcare
4 professionals' knowledge, attitudes and practices relating to quality and safety in nursing homes
5 and home care.
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9 c) Develop theory to guide implementation of future leadership interventions designed to improve
10 the quality and safety in nursing homes and home care.
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14 The following research questions will guide the SAFE-LEAD study:
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- 16
17 1. What are the key contextual factors that affect quality and safety improvement work in the
18 Norwegian nursing homes and home care setting?
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20 2. How can the SAFE-LEAD intervention best be designed to implement use of a leadership guide in
21 nursing homes and home care?
22
23 3. Which contextual factors, including leadership practices and processes influence successful
24 implementation and use of a leadership guide in nursing homes and home care?
25
26 4. How can patient and next-of-kin involvement be integrated into use of a leadership guide and
27 the overall SAFE-LEAD intervention?
28
29 5. What is the impact of the SAFE-LEAD intervention on managers' and staffs' quality and safety
30 knowledge, attitudes, and practice?
31
32 6. What are the implications of the SAFE-LEAD research findings on the development of theoretical
33 frameworks for organizational context, leadership processes, and quality and safety
34 improvement efforts in nursing homes and home care settings?
35
36 7. What are the similarities and differences in contextual factors determining successful
37 implementation of research-based quality and safety improvement tools in Norway and the
38 Netherlands?
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40 8. How and to what extent do the identified key contextual factors explain implementation, uptake,
41 and impact of the SAFE-LEAD intervention across nursing homes and home care services?
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55 **METHODOLOGY**

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Design

The SAFE-LEAD study (2016-2021) applies a convergent parallel mixed-methods design³⁵. We will collect both quantitative and qualitative data in parallel, analyse them separately and compare results subsequently³⁵.

Setting

The main study setting is nursing homes and home care in the Norwegian primary care system. In addition, a small-scale study will take place in a nursing home and a home care institution in the Netherlands.

Study sample and recruitment

Four nursing homes and four home care services from different Norwegian municipalities will be recruited to participate in the SAFE-LEAD intervention. To understand the role of context, the sampling strategy is based on a contrasting case approach³⁶, with selection criteria focusing on diversity in size, geography, and variation between urban and rural services. A similar small-scale study of one nursing home and one home care service will be conducted in the Dutch healthcare setting, allowing for comparison of two countries with different national healthcare and regulatory systems. The recruitment of Norwegian institutions will be conducted in collaboration with two Centres for Development of Institutional and Home Care Services (Rogaland County, Sogn and Fjordane County) and the municipality of Songdalen in Vest-Agder County. The Dutch research team will recruit the institutions in the Netherlands.

Data collection methods and sources

The study is structured around five work packages (WPs) indicating distinct phases of the project. In the following, we describe the phases, data collection and sources.

Phase 1: Guide development, pilot test, and contextual mapping tool (WP1)

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3 In phase 1, we will develop the quality and safety improvement tool – the SAFE-LEAD guide – to be
4 used in the SAFE-LEAD intervention. This includes translation and adaptation of the QUASER Hospital
5 Guide into Norwegian in a process involving the research team in several iterations with professional
6 translation services, co-researchers, future users, and patient and next-of-kin representatives. The
7 original QUASER-guide is based on empirical findings from the hospital setting and the SAFE-LEAD
8 project will develop a version adapted to the Norwegian nursing homes and home care setting. The
9 guide will be in one version similar for both nursing homes and home care. Possible challenges in
10 adapting and further developing a tool, that is originally developed for hospital managers, include
11 different management contexts, tasks, resources, knowledge level among healthcare staff, larger
12 variety in institutional size, resources, and management levels. Therefore, the SAFE-LEAD study has
13 designed a comprehensive development process over the first year in the project period. This
14 development process will consist of internal workshops with the multidisciplinary research team with
15 competence in nursing, homecare, nursing homes, quality and safety, leadership, health promotion,
16 and human factors. There will also be workshops with co-researchers in the SAFE-LEAD partner
17 consortium ensuring sound user involvement with perspectives from patient representatives, next-
18 of-kin representatives, a patient and user ombudsman, and perspectives from future users of the
19 guide (managers in primary care). To ensure that the guide fits the new context, we will conduct 3-4
20 focus group interviews to collect input from managers in nursing homes and home care services who
21 will have read the guide beforehand. Finally, the guide will be tested for fit and validity in one nursing
22 home and one home care service with senior healthcare managers and their teams as part of the
23 pilot test of the intervention (described in phase 2). The two pilot institutions are not part of the
24 sample of eight institutions that will be recruited for the full intervention in Phase 3.

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49 To facilitate implementation and use of the guide, we will also offer a web-based version. The web
50 version will have the same content as the paper version and both the paper and the web-version will
51 be published and publicly available for all Norwegian healthcare services, who may find it relevant,
52 on a SAFE-LEAD website after completion of the project in 2021.

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3 To assess the influence of contextual factors, we will develop a mapping tool for use in the
4 implementation and evaluation phase of the project. This will be inspired by 1) Damschroder et al.'s
5
6 ²⁵ Consolidated Framework for Implementation Research (CFIR) and McDonald's²⁹ framework for
7
8 considering context in quality and safety improvement interventions, 2) additional literature
9
10 searches, and 3) a qualitative study with 10-12 nursing home and home care managers in a variety of
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12 Norwegian municipalities (large, small, rural, urban). In the interviews, we will map the contextual
13
14 factors of relevance for managers' work on quality and safety in nursing homes and home care. The
15
16 interview guide includes open questions regarding which factors managers perceive as important for
17
18 their work with quality and safety, and topics such as external factors, economy, and structure. The
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20 tool will consider factors such as type of healthcare service (nursing home or homecare), funding,
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22 geographical location, organization size, workload, and any ongoing national/regional/organizational
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24 change processes.
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27 28 Phase 2: Intervention design, pilot testing, and recruitment (WP2) 29

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31 The Medical Research Council's guidance on developing, testing and evaluating complex
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33 interventions to improve healthcare^{37 38} will be used to design the intervention. This framework
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35 views healthcare interventions as flexible, non-linear processes, giving equal attention to all process
36
37 phases (development, testing, evaluation, wider application). Furthermore, it stresses the
38
39 importance of context in implementation and allows an intervention to be adapted to its setting, to
40
41 better ensure its success in practice^{37 38}. The application of an organizational perspective has been
42
43 suggested as an aid to understanding the contextual factors and processes that may enable or
44
45 impede knowledge implementation interventions in healthcare settings^{29 39}. As the SAFE-LEAD study
46
47 is concerned with implementation in practice, the Organizing for Quality (OQ) framework^{11 40} will be
48
49 used as a theoretical foundation in the intervention design, alongside the Consolidated Framework
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51 for Implementation Research (CFIR)²⁵. Both frameworks advocate a multi-level contextual
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53 perspective on the implementation and evaluation of interventions.
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The SAFE-LEAD intervention

The SAFE-LEAD intervention will be conducted in two stages over a period of one year³⁷. Stage 1 is a training component involving action learning workshops in which managers and their teams will be able to apply the guide and conduct a self-diagnosis of their current quality and safety work. A team of experienced researchers will facilitate reflexive group discussions among the teams, which will take place in four group sessions (2-3 hours each) in all participating institutions over a six-month period. It is proposed that each group will consist of an extended management team (director of health and care services in municipality, nursing home director/director of homecare services, department managers, head nurses, nursing home physicians, and patient or next-of-kin representatives). These sessions will:

1. Introduce the guide to the participating institutions. This includes rationale, concepts, web-tool, and procedure for an internal management process for use of the guide within the organization.
2. Provide guidance for integrating patient and next of kin experiences in quality and safety improvement work.
3. Establish strategies to address the diagnosed quality and safety challenges.

In Stage 2 of the intervention, a sample of two nursing homes and two home care services (from the total sample of eight institutions) will receive a more comprehensive intervention component consisting of a close collaboration with the researchers. In addition to the training component described in Stage 1, the institutions in stage 2 will receive three site visits by researchers (1-3 days) per institution over a period of 12 months (Stage 1 + Stage 2=12 months). Activities during site visits will include:

1. A workshop to support existing and new learning arenas in quality and safety improvement work (1 day).
2. Observation of and feedback on quality and safety leadership strategy and practices (3 days).

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3 3. A workshop to support the integration of patient and next-of-kin experiences in
4
5 improvement work (1 day).
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8 A pilot test of the Stage 1 intervention will be conducted in one nursing home and one home care
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10 services setting (not part of the sample in the full intervention in phase 3) over a three-month period
11
12 to test the chosen intervention contents, pedagogical approaches, and the functionality of the guide
13
14 developed in Phase 1. We will evaluate the pilot intervention components by means of a qualitative
15
16 process evaluation^{37 38 41} involving observation in the workshops and semi-structured interviews with
17
18 pilot intervention participants (15-20). The pilot will not test the outcome measures. The
19
20 intervention will be tailored based on the pilot results.
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22 23 Phase 3: Testing and evaluating the SAFE-LEAD intervention (WP 3) 24

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26 In Phase 3, we will implement the intervention Stage 1 and 2. Before and during the implementation
27
28 process, we will map contextual factors in all participating institutions by using the context mapping
29
30 tool developed in Phase 1.
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33 The SAFE-LEAD intervention is centred on the testing in practice of a research-based quality and
34
35 safety improvement guide for managers. The Knowledge to Action framework²² will be used to guide
36
37 this part of the intervention. This approach proposes that the translation into practice of a research-
38
39 based guide requires an organisation to identify the problems it needs to solve; adapt the guide to its
40
41 own settings and contexts; assess and address barriers to its use; implement the intervention;
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43 monitor the implementation and evaluate the outcomes⁴². The contents and procedures involved in
44
45 this phase of the SAFE-LEAD intervention will be designed and developed in close collaboration with
46
47 the participating user representatives in the research team, based on a reflexive, dialogue-based
48
49 group technique.
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52 The evaluation of the study entails both an in-depth qualitative work to understand the process of
53
54 implementing the quality and safety improvement guide in practice; how the participating nursing
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3 homes and home care institutions use the guide; and a quantitative measurement of the impact of
4
5 the guide on quality and safety improvement knowledge and practices in these institutions.
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8 Although the SAFE LEAD intervention is a leadership intervention designed to address leadership
9
10 issues, knowledge must be disseminated and applied at the clinical level (e.g., nurses and doctors) for
11
12 the implementation to be effective. In the evaluation of Stage 1, we will assess the relationship
13
14 between using the guide and changes in staffs' and managers' quality and safety knowledge,
15
16 attitudes and practices in all eight participating institutions. We will measure this relationship by
17
18 using a knowledge, attitude and practice (KAP) survey. We will conduct a literature review to identify
19
20 and select measurement scales for the survey questionnaire. Managers and staff in all participating
21
22 institutions will be invited to respond to the baseline survey questionnaire before the intervention
23
24 starts. A second survey questionnaire will be administered to the study participants after the Stage 1
25
26 intervention (after six months). The rationale is to measure changes in quality and safety knowledge,
27
28 attitudes and practices following the intervention program Stage 1.
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32 The purpose of intervention Stage 2 is to establish learning arenas, structures and processes to
33
34 support leaders' self-diagnosis of their quality and safety work, and strengthen their capacity to
35
36 conduct future improvement without researcher involvement. To evaluate the intervention Stage 2,
37
38 we will conduct a process evaluation^{38 41}. The process evaluation will require active researcher
39
40 involvement in the intervention workshops. Data collection to evaluate the intervention processes in
41
42 each of the four institutions (Stage 2) will comprise semi-structured interviews before and after the
43
44 intervention period (over 12 months) with managers (approximately 5-10 x 2 depending on
45
46 institution size) and staff (approximately 8-10 x 2 depending on institution size), observation of the
47
48 intervention workshops and daily practice situations in the selected institutions (40-50 hours), as well
49
50 as document analysis of strategies, plans, and regulatory inspection reports. During the intervention
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52 period, we will also conduct short follow-up conversations with managers participating in the
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54 intervention to collect information for use in the observation and feedback sessions. This implies a
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3 total of approximately 160 semi-structured interviews and 150-200 hours of observation. Interview
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5 guides and observation guides have been developed for managers and healthcare professionals.
6
7 These guides are based on Bate et al.¹¹ and cover quality and safety challenges in terms of culture,
8
9 structure, enthusiasm, education, politics, external demands, physical and technical aspects, use of
10
11 diverse tools in improvement work, and changes to these factors over time at the managerial and
12
13 healthcare professional level. The study will apply NVivo to structure, categorize and analyse the
14
15 qualitative data according to categories relevant for quality and safety improvement challenges¹¹.
16
17 Data will be analysed within cases before conducting the cross-case comparison⁴³.
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20 Across phase 1-3: tracer project on quality improvement in home care (WP4)

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23 To arrive at an in-depth understanding of the role of context and leadership in daily quality
24
25 improvement work, we will include a tracer quality improvement project as part of the data
26
27 collection³³. The tracer project will be studied longitudinally over the entire project period with a
28
29 combination of qualitative interviews, document analysis, observation, and shadowing of staff. In the
30
31 tracer project, we will evaluate an improvement project titled “ABCDE – systematic observation and
32
33 communication in community health care”. The improvement project aims at 1) developing a
34
35 tailored educational program designed to improve healthcare professionals` competencies and skills
36
37 in recognizing and responding to deteriorating frail patients, and 2) implementing new work routines
38
39 in the home care organizations to strengthen healthcare professionals` understanding and clinical
40
41 judgment of deteriorating patients. The tracer project is identified with the project partners and is
42
43 initiated by one of the partner municipalities. The SAFE-LEAD study will examine improvement
44
45 processes in real time as exemplars of how quality improvement is implemented. The tracer project
46
47 will enable lessons learnt, and contribute to understanding how managers are improving the
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49 professional observational skills of their staff in the home care context.
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53 Phase 4: Mixed-methods synthesis, cross-country comparison, theory development (WP5)
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3 The SAFE-LEAD study is an opportunity to understand the meaning and impact of contextual factors
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5 by analysing the influence of the quality and safety improvement guide implementation via three
6
7 data sets: 1) a quantitative survey of outcome measures (knowledge, attitudes, practice) across a
8
9 sample of eight institutions, 2) a context mapping of all participating institutions, and 3) a qualitative
10
11 multiple case study with a smaller sample of four institutions providing rich information on
12
13 leadership processes and practices, a small-scale implementation case study in the Netherlands, and
14
15 a tracer quality improvement project. In this sense, the study pays closer and more explicit attention
16
17 to multiple contextual factors^{44 45}, and the way in which they affect the success and sustainability of
18
19 implementing quality and safety improvement tools.
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22 The different data sets will be collected in parallel and analysed separately³⁵. In Phase 4 of the study,
23
24 we will synthesise the results from the qualitative, quantitative, and context data sets by using a
25
26 procedure called “joint display of data”³⁵. The researchers will jointly display all forms of data (e.g., in
27
28 tables or in NVivo) responding to similar concepts and research questions. The analysis of the total
29
30 amount of data in the Norwegian part of the study will compare the results from the concepts
31
32 measured in the KAP survey, and what is mapped by qualitative process evaluation methods, and the
33
34 findings from the tracer project. The outcomes of the analyses will be used to develop theoretical
35
36 frameworks and conceptual models of the influence of context and leadership on quality and safety
37
38 improvement work in primary care settings.
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42 The Norwegian results will then be compared with Dutch results from a similar small-scale research
43
44 project, focusing on managers’ use of different quality and safety improvement tools in general (i.e.
45
46 not the SAFE-LEAD guide in specific). The Dutch cases are used to contrast the nursing homes and
47
48 home care in Norway, as the Dutch healthcare system frequently uses a greater range of
49
50 improvement tools as part of managing quality and safety than the Norwegian. The cross-country
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52 analysis will compare and contrast managers’ practice and competence, and whether staff members
53
54 make changes in their work practice to improve quality and safety of service provision. The
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3 comparison will build on a contrasting case approach ⁴³ based on the differences between the
4
5 organisation of quality and safety work in healthcare systems in the two countries. Building on the
6
7 approach taken in the QUASER study³³, a multilevel perspective will be used, considering important
8
9 macro-level contextual factors (national healthcare system), in addition to the factors identified at
10
11 the meso and micro levels in the case studies. We will look at effects of different contextual factors
12
13 such as funding frameworks, regulation, prioritisation, organisation, and competence level. National
14
15 differences will be analysed to better understand the effect of macro-level healthcare system factors
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17 on the success of quality improvement implementation processes.
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20 **ETHICS AND DISSEMINATION**

21 **Ethical reflections**

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26 The SAFE-LEAD leadership-focused intervention targets a potential knowledge gap among managers
27
28 and supports their work on quality and safety improvement. The risk of negative effects on patient
29
30 outcomes is thus minimal. The potential of not having a positive effect of the intervention on
31
32 managers' leadership competence is present, but the risk of negative patient outcome due to this is
33
34 limited. The patient and next-of-kin perspectives are key throughout the SAFE-LEAD study. Patients
35
36 and next-of-kin representatives participated in the project development and will collaborate with
37
38 the project team as co-researchers throughout the project period. Different measures are involved
39
40 in the quality and safety improvement guide itself (strategies, measures) and in the intervention
41
42 components (workshops on use of patient experiences) to improve managers' abilities to involve
43
44 patient and next of kin in improvement work.
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48 The SAFE-LEAD study is approved by the Norwegian Centre for Research Data (2017/52324 and
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50 54855), and exempted from ethical approval from Regional Ethical Committee because no health
51
52 information will be collected. The Norwegian approval also includes approval for data collection in
53
54 the Netherlands. The Dutch ethical approval system does not require ethical approval for research
55
56 projects not involving patient data, as in the SAFE-LEAD study. All participants will sign informed
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3 consent and will be recruited on a voluntary basis. No patient records or other patient data will be
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5 collected.

6 7 **Dissemination**

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10 The SAFE-LEAD partners have agreed upon publication guidelines, a publication strategy, and a
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12 publication plan. The publication strategy consists of dissemination in scientific peer-reviewed
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14 journals, books and presentations at academic conferences. Moreover, there is a strategy to ensure
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16 dissemination in popular science forums and in social media. The project has established a SAFE-
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18 LEAD web page, a SAFE-LEAD Facebook account, newsletters, and posters. The project has an
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20 international expert advisory board that will be invited annually to give input to the study and
21
22 contribute to the sharing of results.
23

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25 The publication plan will evolve over time but includes the following planned scientific dissemination
26
27 activities:

- 28
29 • Two PhD theses (authors Terese Johannessen and Torunn Strømme).
- 30
31 • 18-20 scientific articles in a peer-reviewed special issue and in different peer-reviewed journals.
- 32
33 • A book on Quality and Safety in Primary Care involving international contributions.
- 34
35 • Local seminars at the study sites (including user groups).
- 36
37 • Norway-Netherland seminar in 2020 to present final project results. Open seminar with target
38
39 group healthcare managers, inspection authority, researchers, user groups, professional
40
41 associations, governmental bodies, etc.
- 42
43 • Special sessions at the 5th and 6th Nordic Conference on Research in Patient Safety and Quality
44
45 in Healthcare.
- 46
47 • Presentations at regional, national and international conferences.
- 48
49 • Popular science presentations in national media and healthcare magazines.

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52 Ten primary publications are planned (see Table 1):
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Table 1. Planned primary publications from the SAFE-LEAD study

Articles	Planned Scientific Article	Main data source
Article 1	Improving Quality and Safety in Nursing Homes and Home Care: The study protocol of a mixed methods research design to implement a leadership intervention.	Literature Policy documents Scientific methods
Article 2	Mapping of contextual factors in nursing homes and home care - a mixed methods design.	Literature review Context mapping Semi-structured interviews
Article 3	Designing an intervention for improving leadership of quality and safety in nursing homes and home care.	Semi-structured interviews Partner workshops
Article 4	Literature review of measurement scales of relevance for mapping quality and safety knowledge, attitudes, and practice in nursing homes and home care.	Literature review
Article 5	Understanding the role of a leadership intervention on quality and safety leadership processes.	Process evaluation including semi-structured interviews, focus group interviews, observation
Article 6	The impact of a leadership intervention on quality and safety knowledge, attitudes and practice in nursing homes and home care.	Quantitative data from KAP survey
Article 7	Implementation of a quality and safety improvement guide and effects on quality and	Mix: KAP survey

	safety work in a nursing home context.	Process evaluation Context mapping
Article 8	Implementation of a quality and safety improvement guide and effects on quality and safety work in a home care context.	Mix: KAP survey Process evaluation Context mapping
Article 9	The meaning of context: Comparing the implementation of a quality and safety improvement guide in the nursing home and home care context	Mix: KAP survey Process evaluation Context mapping
Article 10	Cross country comparison of working on quality and safety in Norwegian and Dutch nursing homes and home care services.	Mix: KAP survey Process evaluation Context mapping

AUTHORS' CONTRIBUTIONS

SW and KAa applied for funding of the SAFE-LEAD study to the Research Council of Norway, (RCN), planned the study design and study protocol, and contributed to the development of the data collection tools. SW and ER drafted the manuscript, with substantial input from KAa, and revised it based on comments from all co-authors. ER contributed to the study design, development of data collection tools, and was responsible for the application for approval of the study to the Norwegian Centre for Research Data. Authors TS, TJ and MS contributed to the study design and development of data collection tools, and commented on the draft. Authors HvB and RB contributed to the study design and development of the data collection tools, commented on the draft, and are responsible

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2
3 for the Dutch part of the study. Authors IAa, BU, EHR, LHT, and ATSP contributed to the study design
4
5 and have commented on the draft. All authors have approved the final version of the manuscript.
6

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8
9
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11
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13

14 **COMPETING INTEREST**

15
16
17 The authors declare there are no conflict of interest.
18
19

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21
22
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24
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26
27 who played a key role in developing the grant application to the RCN, and to the Patient Ombudsman
28
29 Vestfold Torunn Grinvoll, senior representative Elsa Kristiansen, and Lene Schibeveaag in the SAFE-
30
31 LEAD project who have provided input to the study design and development.
32

33
34 The leadership guide applied in the SAFE-LEAD study is based on the results from the study *Quality*
35
36 *and Safety in European Union Hospitals: A Research-based Guide for Implementing Best Practice and*
37
38 *a Framework for Assessing Performance (QUASER)*. The QUASER project received funding from the
39
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43
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45
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47
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49
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