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Development of a codesigned complex intervention to prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes in Sweden - The STAIR OF KNOWLEDGE

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Title

Development of a codesigned complex intervention to prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes in Sweden - The STAIR OF KNOWLEDGE

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Abstract

Objectives: To describe the development of a codesigned complex intervention intended to prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes.

Design: This part of a two-arm pragmatic cluster randomized controlled trial focused on developing a codesigned complex intervention. The development of the current intervention was inspired by the Medical Research Council guidelines for complex interventions and the action part of the knowledge-to-action framework and was intended to work in a real-world setting.

Setting: Nursing homes in southern Sweden.

Participants: Nurse aides, registered nurses and managers in nursing homes codesigned the intervention together with the research group in workshops. Key persons working in the municipality who were considered to play an important role in the development of the intervention also participated throughout this process in a dynamic and iterative way.

Results: The codesigned intervention, the STAIR OF KNOWLEDGE, is intended to bridge the evidence-practice gap regarding the entire preventive care process of the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes. The intervention is aimed at nurse aides, registered nurses and managers. The intervention lasts for three weeks and is divided into two parts. In part one, nurse aides, registered nurses and managers obtain knowledge on their own by following written instructions. In part two, they meet, interact and discuss the knowledge acquired during part one.

Conclusion: The current codesign complex intervention, the STAIR OF KNOWLEDGE, which aims to prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes, is robustly developed and thoroughly described. The description of the entire development process may enhance the replicability of this intervention. The intervention needs to be tested and evaluated in an upcoming feasibility study.

Trial number: Clinical Trial NCT05308862.

Strengths

- Inspired by the Medical Research Council guidelines for complex intervention, a robust development process was undertaken based on the literature and research conducted in the local context prior to developing the complex intervention.
- A complex intervention was codesigned both with and for nurse aides, registered nurses and managers in workshops. Additionally, key persons working in the municipality were engaged in the development of this tailored intervention.
- To bridge the evidence-practice gap regarding the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes, knowledge translation strategies were applied during the development process in accordance with the action part of the knowledge-to-action framework.
- A thorough description of the entire development process may enhance the replicability of the current intervention.

Limitations

- One limitation of the development process was that this design is time- and resource-consuming. On the other hand, this was necessary to develop a tailored complex intervention that might enhance the likelihood of successful implementation.

Introduction

There remains an evidence-practice gap in preventing the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes^{1 2}. These health risks cause a major burden for older persons³ and they are costly for the health care system⁴. Since older persons are more vulnerable to these health risks⁵ and considering the increasing ageing population globally, particularly with regard to older persons aged 80 years or older⁶, evidence-based preventive work is crucial to manage this demographic challenge and, importantly, these health risks among older persons.

In Sweden, there is a national quality register, Senior Alert, providing an individualized, standardized, structured and systematic preventive care work process for older persons 65 years or older who are at risk of pressure ulcers, malnutrition, poor oral health and falls⁷. Senior Alert provides evidence-based knowledge aimed at preventing these health risks to enable a healthy ageing among older persons⁸; in addition, it can increase cost efficiency⁹. However, a lack of knowledge among those working with older persons has been identified as one major challenge regarding to preventive work^{2 10}. As a result, these health risks continue to be prevalent⁷. For instance, approximately every third older person living in a nursing home faces at least one of these health risks, and every tenth older person faces all four of these health risks¹. Additionally, not all older persons who are at risk have planned care interventions^{11 12}, and there is a mismatch between identified risks and planned and performed care interventions^{13 14}, thus indicating an evidence-practice gap and consequently, highlighting the urgent need of translating knowledge into practice.

Nevertheless, this is not unique to Sweden or this context; in contrast, health systems worldwide face the shared challenge of translating knowledge into practice¹⁵. Knowledge translation has been defined as “*a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve health care of people in the country, provide more effective health service and products and strengthen the health care system*”, p. 165¹⁶. Ineffective knowledge translation can result in an evidence-practice gap¹⁷ and, worryingly, lead to situations in which patients are denied interventions that have been proven to be beneficial¹⁸, which in turn can result in a reduction in their quality of life¹⁹.

To bridge this evidence-practice gap, conceptual frameworks are recommended²⁰. The knowledge-to-action (KTA) framework is intended to help the parties involved in the process of knowledge translation¹⁸. The KTA framework is also appropriate when addressing an evidence-practice gap¹⁵ and conducting pragmatic research¹⁸.

As a part of translating knowledge into practice and promoting knowledge use by end users²¹, the engagement of both researchers and stakeholders in research is crucial²². Engaging stakeholders at an early stage in the development of solutions that can be applied to real world settings is essential according to the Medical Research Council's (MRC) framework for complex interventions²³. Complex interventions have multiple components, target multiple groups or levels of an organization and attempt to affect multiple outcomes²³. Additionally, for complex interventions to be most useful to end users, the local context must be taken into account²⁴. Since it is well underpinned that organizational factors hinder preventive work in nursing homes^{2 25}, considering and understanding the local context and integrating it into the process of intervention development is crucial²⁶.

Consequently, change in the practices of nursing homes is considered to be complex²⁷, but if complex interventions are tailored to the local context²⁸, including the targets of the intervention^{23 24} and is directly relevant to them²⁹, such interventions could be successful.

Aim

The aim of this article is to describe the development of a codesigned complex intervention intended to prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes.

Methods

Definitions

Nursing homes were defined based on the definition provided by Neziraj et al. (2021)¹: older persons receiving municipal health care in residential care homes.

Health care personnel and managers were defined based on the definition provided by Neziraj et al. (2021) as follows²:

Nurse aide: a person with a secondary degree in nursing, involves three years of study in high school *or* a person without any formal education in nursing.

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3 *Registered nurse*: a person with a bachelor's degree in nursing, which involves three years of
4 study at university.
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7 *Manager*: a person who is in charge of nurse aides or registered nurses.
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10 *End-users*: nurse aides, registered nurses and managers working in nursing homes.
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12 *Stakeholders*: key persons working in the municipality who are considered to play an
13 important role in the development and implementation of the intervention.
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16 **Study context and setting**

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18 In nursing homes, nurse aides are the main providers of care and services and are on duty
19 around the clock. Nurse aides work under the regulations of the Social and Services Act
20 (SFS)³⁰ but are also delegated tasks according to the Health and Medical Services Act
21 (HSL)³¹, usually by registered nurses. Registered nurses guide care in nursing homes and
22 work under the regulations of HSL³¹. In the current setting, a large town located in southern
23 Sweden, one registered nurse (or occasionally more depending on the size of the nursing
24 home) is located in the nursing home during office hours but is also available at any other
25 time. Managers who are in charge of the care and services provided by the nurse aides are
26 located at their respective nursing homes during office hours.
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34 **Study design**

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37 This part of the PROSENIOR project and a two-arm pragmatic cluster randomized controlled
38 trial focused on the development of a codesigned complex intervention. The development of
39 the current complex intervention (hereafter called simply the intervention) was conducted in a
40 pragmatic paradigm as it is intended to work in a real-world setting²⁹; this process was
41 inspired by the MRC guidelines for complex interventions²⁴, applied the KTA framework¹⁸
42 and engaged end-users and stakeholders in the process of codesign³².
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48 We follow the guidance for reporting intervention development studies (GUIDED)³³ when
49 describing the development of the intervention and the template for intervention description
50 and replication (TIDieR) checklist and guide³⁴ when describing the intervention. We use
51 “development” to refer to the whole process of intervention development and “design” to
52 indicate the intervention content, format and delivery.
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57 **Patient and public involvement**

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3 Patients were not involved in the research process. End users codesigned the intervention with
4 the research group in workshops. Stakeholders were also involved in this research; they
5 supported the research group throughout the entire development of the intervention by
6 contributing their valuable knowledge. All engagement is described in detail in the section
7 “Development of the intervention” below.
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10 11 12 **Development of the intervention**

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14 We developed the intervention in three phases and applied the KTA framework in all phases
15 (Figure 1).
16

17 18 *Theory*

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20 The KTA framework takes implementation strategies into account already in the development
21 phase¹⁸, which promotes and sustains practice change¹⁵. We applied the KTA framework
22 because it offers a structured and systematic approach to translate knowledge into practice¹⁸.
23 It comprises two parts: knowledge creation and the action cycle. Since evidence-based
24 knowledge is already available to end users in the quality register Senior Alert, the action
25 cycle was applied during the development of the current intervention. The action cycle
26 consists of the following steps: *1. Identify the problem, identify and review selected*
27 *knowledge, 2. Adapt knowledge to the local context, 3. Assess barriers to knowledge use, 4.*
28 *Select and tailor implementation strategies, 5. Monitor knowledge use, 6. Evaluate the*
29 *outcomes and 7. Sustain knowledge use*^{18 35}. Steps 1-4 the action cycle were applied
30 throughout the development process of developing the intervention in an iterative, dynamic
31 and permeable way.
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42 43 *Phase one*

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45 During this phase, we established contact with stakeholders in the municipality, searched for
46 relevant literature and conducted studies in the local context.
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48 49 *Establishing contact with stakeholders in the municipality*

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51 Initially, we established contact and met with the head of the nursing homes in the
52 municipality. In addition, a reference group was created, which consisted of experts drawn
53 from the local context.
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56 57 *Searching for literature and conducting studies in the local context*

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3 As a part of step 1 in the KTA framework, *identify the problem, identify and review selected*
4 *knowledge*, we first searched for literature regarding the risks of pressure ulcers, malnutrition,
5 poor oral health and falls and intervention studies in this area (unpublished project plan).

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8 Subsequently, we conducted a cross-sectional study to determine the prevalence of the risks
9 of pressure ulcers, malnutrition, poor oral health and falls in nursing homes in southern
10 Sweden¹.

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14 As a part of steps 2-3 in the KTA framework, *adapt knowledge to the local context and assess*
15 *barriers to knowledge use*, we conducted focus group interviews with end users who worked
16 in nursing homes to prevent pressure ulcers, malnutrition, poor oral health and falls². A
17 detailed description of this study and its participants is provided in Neziraj et al².

18
19
20 Additionally, we asked the end users included in this study how an optimal intervention could
21 be designed to prevent the risks of pressure ulcers, malnutrition, poor oral health and falls
22 among older persons in nursing homes. These data were specifically targeted at the current
23 part of the trial and were therefore not included in our published study, i.e., Neziraj et al².

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28 Phase one suggested that individuals working with older persons in nursing homes need
29 increased knowledge concerning how to prevent these health risks. Since existing evidence
30 and knowledge concerning how to prevent these health risks is already contained in Senior
31 Alert, the challenge seems to lie in the evidence-practice gap, which highlights the need for
32 support to be provided to end users with regard to translating evidence into practice^{1 2}.

33 34 35 36 37 ***Phase two***

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40 During this phase, we recruited and randomized nursing homes, invited end users in the
41 intervention arm to participate in workshops, and planned and conducted the workshops. We
42 also analysed the specific data regarding intervention design drawn from the focus group
43 interviews (see the previous paragraph on phase one for clarification) and the workshops.

44 45 46 47 ***Recruiting and randomizing nursing homes***

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49
50 Inclusion criteria for the trial were nursing homes working with and registered in the quality
51 register Senior Alert. We recruited eligible nursing homes (n=21) to participate in the trial via
52 digital meetings. In total, eight nursing homes agreed to participate and were cluster
53 randomized using a computerized program to either the intervention (n=4) or control arm
54 (n=4). The nursing home is the cluster and the unit of allocation. Due to the nature of the
55 design, the cluster randomization of nursing homes was unblinded. Subsequently, we invited
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3 end users (n=118) working in nursing homes in the intervention arm to participate in
4 workshops intended to develop a tailored intervention together with the research group; the
5 invitations were extended both via a digital information video and in written form. The
6 remaining end users (n=184) working in the nursing homes who were allocated to the control
7 arm continued with their usual care routine (Figure 2).
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10 11 12 *Conducting workshops*

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14 As a part of steps 2-4 in the KTA framework, *adapt knowledge to the local context, assess*
15 *barriers to knowledge use and select and tailor implementation strategies*, we conducted
16 workshops with end users. In total, four workshops were conducted, which featured two nurse
17 aides, one registered nurse and one manager in each workshop; the workshops were
18 conducted over the course of four weeks (March-April 2022). A majority of the end users
19 (n=16) were women (n=13), between the ages of 28-63 years (mean 53), and had worked for
20 3-41 years (mean 18). The workshops were kept small to offer the end users the possibility of
21 exhibiting activity and creativity³⁶. The first author (MN) led the workshops together with one
22 of the coauthors (all coauthors participated in one workshop each). The workshops were
23 intended to serve as a place in which participants could learn together and discuss the design
24 of the intervention in four different stations (Table 1). The end users engaged in active
25 discussion and wrote creative ideas and suggestions on the walls and the board in a lecture
26 hall designed for the purpose of encouraging creative pedagogy (Figure 3). In the first station,
27 the end users were asked to discuss the risks of pressure ulcers, malnutrition, poor oral health
28 and falls and the care interventions that should be applied. In the second station, they were
29 asked to discuss and identify barriers and facilitators they had encountered in their own work
30 regarding the preventive care process stipulated by Senior Alert (identify a risk, assess causes
31 and plan, undertake and evaluate care intervention). Barriers were written down on pink post-
32 it notes, while facilitators were written down on green post-it notes. These post-it notes were
33 subsequently placed at the appropriate location on the board with regard to the predawn
34 preventive care process. The focus of the discussions at station three was on the end-users'
35 needs and the support they needed throughout the preventive care process. In the fourth
36 station, they were asked to discuss the core components of the intervention, how to provide
37 follow-ups and implementation strategies. After completing each workshop, MN
38 photographed and briefly summarized the written data from each station. This summary was
39 used if the end users in the subsequent workshop reached an impasse and/or discussed and
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Table 1. Workshop content (n=4).

Workshop	Station	Content	Examples of questions to discuss
Workshop 1-4	Station 1	Case regarding an older person at risk of pressure ulcers, malnutrition, poor oral health and falls living in a nursing home	<ul style="list-style-type: none"> • What would you have done in this case regarding these four risks? • Are there any good examples? What can you learn from good examples? • What additional knowledge do you need regarding these four risks in order to produce a risk assessment and provide adequate care interventions?
	Station 2	Senior Alert's care process	<ul style="list-style-type: none"> • Place green/pink post-it notes on the care process regarding what works/what can be improved in your own work and workplace.
	Station 3	End-users needs' and the support they need regarding preventive work	<ul style="list-style-type: none"> • What do you need in your preventive work? • Why is this important, and what is most important (rank 1-3)? • Who needs help in the context of preventive work? • Who should be involved and in what way? • What is necessary for it to be feasible? • How can you work better/smarter? • How can you work in a more sustainable way?
	Station 4	Core components of the intervention	<ul style="list-style-type: none"> • What should be included in the intervention? • Who should it target? • How should it be designed? • How much/often/for how long should the intervention take place? • How should it be followed up? • Where should it be implemented? • How should it be implemented?

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3 wrote similar suggestions and ideas to those proposed by the end users in the previous
4 workshop. Each workshop lasted for three hours, and the discussions were audio recorded to
5 support the written data collection during the analysis.
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8 *Analysing the data from the focus group interviews and the workshops*

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11 The analysis was guided by the six phases of reflexive thematic analysis described by Braun
12 and Clarke^{37 38}: 1. *Familiarizing with the data*, 2. *Coding*, 3. *Generating initial themes*, 4.
13 *Reviewing the identified themes*, 5. *Defining and naming the themes* and 6. *Producing the*
14 *report*. Thematic analysis was chosen because it facilitates a flexible analysis process but
15 simultaneously provides researchers with the core skills they need to conduct the analysis.
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20 To familiarize ourselves with the data, MN and MA read the transcripts from the focus group
21 interviews, including the data specifically collected for the current part of the trial, and the
22 written data collected from the workshops. In addition, MN listened to all the audio-recorded
23 discussions from the workshops meticulously. During the process of reading the data, MN and
24 MA reflected on and generated initial codes. Subsequently, MN and MA met and discussed
25 these initial codes (1). Thereafter, MN and MA separately engaged in a process of identifying
26 and coding entities of interest in relation to the design of the intervention, giving equal
27 attention to all the data (2). The initial codes were then sorted into their core components in
28 relation to the design of the intervention (3). Next, the core components were reviewed by
29 MN to determine whether any relevant data regarding the design of the intervention had been
30 missed (4). Subsequently, MN designed an outline of the intervention. This outline contained
31 the intervention's proposed design, including its content, format, plan for delivery and
32 duration. In the following step of the analysis, the entire research group met and discussed the
33 design of the outline of the intervention. During this step, MN continuously revised the
34 outline of the intervention following discussions within the research group (5). Then, the
35 outline of the intervention was redesigned by MN. The redesigned outline of the intervention
36 was then presented to the research group before it was presented to the stakeholders. The
37 process of producing the final design of the intervention is described in phase three below (6).
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51 ***Phase three***

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54 As part of steps 2-4 in the KTA framework, *adapt knowledge to the local context, assess*
55 *barriers to knowledge use and select and tailor implementation strategies*, MN and MA met
56 regularly with stakeholders to present and discuss the outline of the intervention. MA works
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3 within the municipality and thus facilitated contact with stakeholders who were considered to
4 play an important role in this part of designing the intervention. Since this part of the process
5 was dynamic and iterative and because all relevant uncertainties had not been addressed in the
6 redesigned outline of the intervention, it was helpful to meet stakeholders for the purpose of
7 identifying and addressing the remaining uncertainties regarding the content, format, delivery
8 and duration of the intervention. This part of the process was time-consuming and required a
9 back-and-forth process involving meetings and discussions between MN and MA, within the
10 entire research group and with the stakeholders. Next, the redesigned outline of the
11 intervention was adjusted by MN in accordance with the results of these meetings and
12 discussions (Figure 4). Finally, MN investigated whether any data from the focus group
13 interviews and the workshops had been missed, since these data were intended to serve as the
14 foundation for designing the final outline of the intervention. The final outline of the
15 intervention, the STAIR OF KNOWLEDGE (Figure 5), is described below.

26 Results

29 The final design of the intervention

31 The STAIR OF KNOWLEDGE consists of *the foundation and stairs 1-6*, lasts for three
32 weeks and is divided into two parts. Part one, including *the foundation and stairs 1-5*, takes
33 place throughout the entire intervention period (weeks 1-3) and is delivered digitally to end
34 users in the nursing homes via their workplace email addresses. Part two includes *stair 6* and
35 takes place during the last week of the intervention period (week 3) in the nursing homes in
36 question.

37 In part one, *the foundation and stairs 1-5*, end users obtain knowledge on their own by
38 following written instructions. *The foundation and stairs 1-5* provide end users with website
39 links that allow them to both read texts and watch videos. *The foundation* provide end users
40 with knowledge and awareness of how to work preventively in the context of an existing local
41 working routine and is intended to represent “the ground to stand on”. *Stairs 1-4* provide the
42 end users with general knowledge drawn from the quality register Senior Alert regarding the
43 risks of pressure ulcers, malnutrition, poor oral health and falls (*stair 1*), risk assessment
44 instruments (*stair 2*), the underlying causes of these risks (*stair 3*) and preventive care
45 interventions (*stair 4*). *Stairs 1-4* are mandatory for all professionals. *Stair 5* provides end
46 users with knowledge of how to register in the quality register Senior Alert and is mandatory
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3 only for users who have access to and the responsibility to register in the quality register
4 Senior Alert.
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7 In part two, *stair 6*, MN meets with end users to interact with them and discuss the knowledge
8 acquired during part one. Part two is intended to inspire end users to prevent the risks of
9 pressure ulcers, malnutrition, poor oral health and falls. MN moderates the sessions, which
10 last approximately 30 minutes each and are held Monday to Friday in the nursing homes in
11 question based on the content of part one. In these sessions, end users are, for instance, asked
12 to perform risk assessments of different cases, identify the underlying causes and plan for
13 accurate care interventions. End users are also asked to identify environmental risk factors
14 related to the risks of pressure ulcers, malnutrition, poor oral health and falls in their own
15 workplace and to discuss and generate ideas concerning how to follow up on the preventive
16 care process at the organizational level.
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25 Discussion

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27 The current codesigned complex intervention, the STAIR OF KNOWLEDGE, was developed
28 together with end users in workshops in an active and creative way. Stakeholders were also
29 engaged in an iterative and dynamic way throughout the development of the intervention, as
30 an important part of undertaking implementation strategies already in the development
31 phase³⁹. As recommended by the MRC framework²⁴, we meticulously considered the
32 relationship between the intervention and its context when developing the intervention.
33 Furthermore, we followed the strategies for knowledge translation included in the KTA
34 framework¹⁸. Hence, the strengths exhibited by the development of this complex intervention
35 lie in the fact that it was developed both together with and for end users and engaged
36 stakeholders who are considered to play an important role in the development and
37 implementation process. The current intervention is intended to work in a real-world setting
38 and aims to bridge the evidence-practice gap regarding the process of preventing the risks of
39 pressure ulcers, malnutrition, poor oral health and falls; ultimately, this intervention may
40 reduce these risks among older persons in nursing homes.
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52 The benefits of codesign are potentially substantial⁴⁰. For instance, engaging end users and
53 stakeholders as design partners to the research group could ensure that the intervention
54 exhibits a better fit to their needs³². Engaging end users and stakeholders early enables their
55 experiences and requirements to be taken into account at the start rather than a situation in
56 which the researchers presume to know what is required³⁹. In the current development
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3 process, although end users' and stakeholders' engagement ranged in intensity from relatively
4 passive to highly active, their engagement pervaded the entire development process, and
5 important decisions regarding the intervention design were made by considering their input.
6 Furthermore, because we engaged end users and stakeholders, the current intervention was
7 based on their own experiences regarding the evidence and knowledge that are necessary
8 throughout the entire process of preventing the risks of pressure ulcers, malnutrition, poor oral
9 health and falls. Engaging end users and stakeholders during the developing process⁴¹ was
10 also important in light of the local context since this enabled us to identify facilitators and
11 barriers in the environment in which the intervention will eventually be implemented²⁶.

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19 Considering and understanding the local context is also crucial when addressing an evidence-
20 practice gap²⁴. In this case, knowledge concerning the process of preventing the risks of
21 pressure ulcers, malnutrition, poor oral health and falls is already contained in the quality
22 register Senior Alert, but this evidence has not been fully translated into practice. Thus, we
23 focused on translating the existing knowledge contained in Senior Alert into practice.
24 However, if this knowledge is to be implemented effectively⁴², it is crucial to employ a
25 conceptual framework²⁰. Therefore, we chose the KTA framework because it provided us
26 with knowledge translation strategies to reduce the evidence-practice gap¹⁸, and it was
27 suitable since the quality register Senior Alert is already in use. Furthermore, adapting
28 knowledge to the local context and assessing barriers to knowledge use may enable the
29 research to have a greater impact⁴³, which could in turn reduce the evidence-practice gap.

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39 Successful intervention development is characterized as rigorous and scientific and leads to an
40 intervention that can be implemented in a real-world setting³³. The robust research process
41 used to develop the STAIR OF KNOWLEDGE intervention incorporates existing evidence,
42 the views of end users and stakeholders⁴⁰, the local context and knowledge translation
43 strategies. Consequently, the use of knowledge translation strategies and the engagement of
44 end users who are embedded in the local context in the development of a tailored complex
45 intervention both for and with them could contribute to increased knowledge and awareness
46 of the entire process of preventive care. This may, in turn, reduce the evidence-practice gap
47 among end users and, importantly, reduce the risk of pressure ulcers, malnutrition, poor oral
48 health and falls among older persons in nursing homes. Furthermore, the engagement of
49 stakeholders already in the development process is likely to facilitate the implementation of
50 the current intervention.
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Limitations

Although the development of this complex intervention has been completed, it is important to acknowledge the limitations of the development process. First, only four clusters were included in the development process. Nevertheless, since this part of the trial focused on the development of an intervention rather than its evaluation and because the clusters were recruited pragmatically, the clusters included in the trial could be considered sufficient. Second, although all end users in the intervention arm (n=118) were invited to participate in workshops, only 16 participated. However, different professionals participated in the workshops, and the discussions were energetic, active and creative. Third, although this design is creative and can generate new ideas, it is time- and resource-consuming for all parties involved. It requires end users and stakeholders to set aside time and expend extra effort in their daily work. For researchers, this process requires careful planning to enable them to coordinate, meet with many different persons repeatedly and be responsive to all parties involved. However, although this design required the expenditure of time and resources, the engagement of end users, stakeholders and researchers is meaningful and necessary to develop successful interventions; ultimately, this design might have an impact on to prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes. Furthermore, the current intervention might offer value when used by others and could likely be adjusted to and tested in similar contexts.

Conclusion

The current codesign complex intervention, the STAIR OF KNOWLEDGE, which aims to prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes, is robustly developed and thoroughly described. A careful description of the entire development process and the intervention itself can enhance the replicability of the current intervention. This article highlights the extensive process that is necessary for the development of tailored complex interventions. Finally, this codesigned complex intervention might result in more evidence-based practice concerning the entire process of preventing the risks of pressure ulcers, malnutrition, poor oral health and falls and, importantly, reduce these health risks among older persons in nursing homes. However, uncertainties regarding the intervention itself remain. Thus, the STAIR OF KNOWLEDGE must be tested and evaluated in an upcoming feasibility study before we continue to the stage of conducting a full trial evaluation.

Ethical considerations

This trial was approved by the Swedish Ethical Review Authority (DNR 2019-06414). In addition, written approval was requested and granted by the head of the department of elderly care homes in the municipality in which this trial was conducted. All end users working in eligible nursing homes were invited to participate in the workshops. Moreover, end users had the right to withdraw from participation at any stage without providing reasons and bearing any consequences. Participation in the workshops was based on written consent. The results of this trial may be considered to contribute to scientific value on good ethical grounds, and the benefits of participating in the trial outweigh the corresponding risks.

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Authors' contributors

All the authors contributed to this part of the trial in terms of conception, planning and design. MN coordinated the workshops and meetings with stakeholders. MN led all the workshops, and all coauthors participated in one workshop each. MN and MA analysed the data collected from the focus group interviews (i.e., the data that were specifically collected for inclusion in the current part of the trial) and the workshops. All authors interpreted the results. MN drafted the design of the intervention, and all coauthors revised the intervention in regard to its design. MN drafted the manuscript, and all coauthors supervised and revised the manuscript with respect to important intellectual content. All the authors read and approved the final version of the manuscript.

Competing interests

The authors have no conflicts of interest.

Participant consent

All participation in the workshops was based on written consent.

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1
2
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7 financial support.
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12 **Data sharing statement**

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14 The data that support the development of the STAIR OF KNOWLEDGE intervention are not
15 publicly available to ensure confidentiality. All data relevant to the development are included
16 in the article. All figures and tables included in this article are original.
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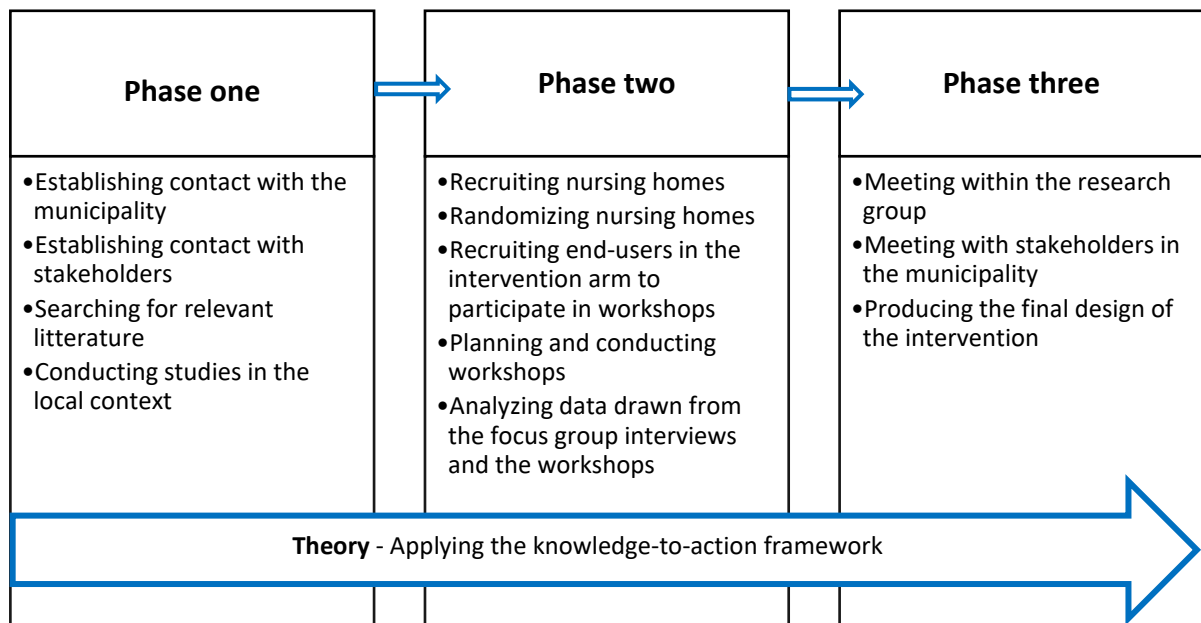


Figure 1. Phases one-three illustrate the process of developing the STAIR OF KNOWLEDGE intervention, which took place between 2019 and 2022. Although the knowledge-to-action (KTA) framework is viewed as a cycle by Graham and colleagues (2006), in this figure, the arrow illustrates the fact that the KTA framework was applied throughout phases one-three of the development process. The KTA framework was applied in an iterative and dynamic way in each phase and is described in detail in the text.

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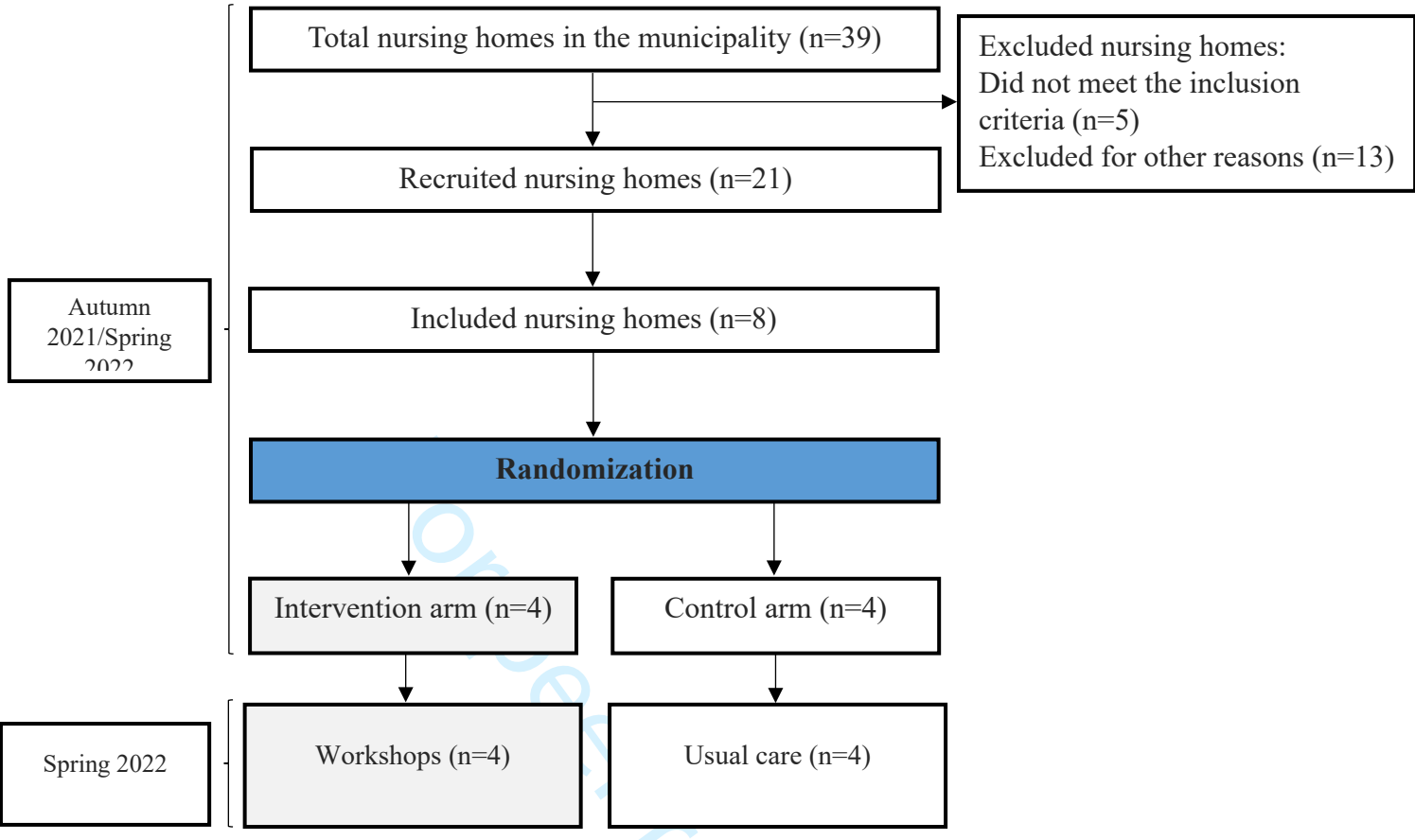
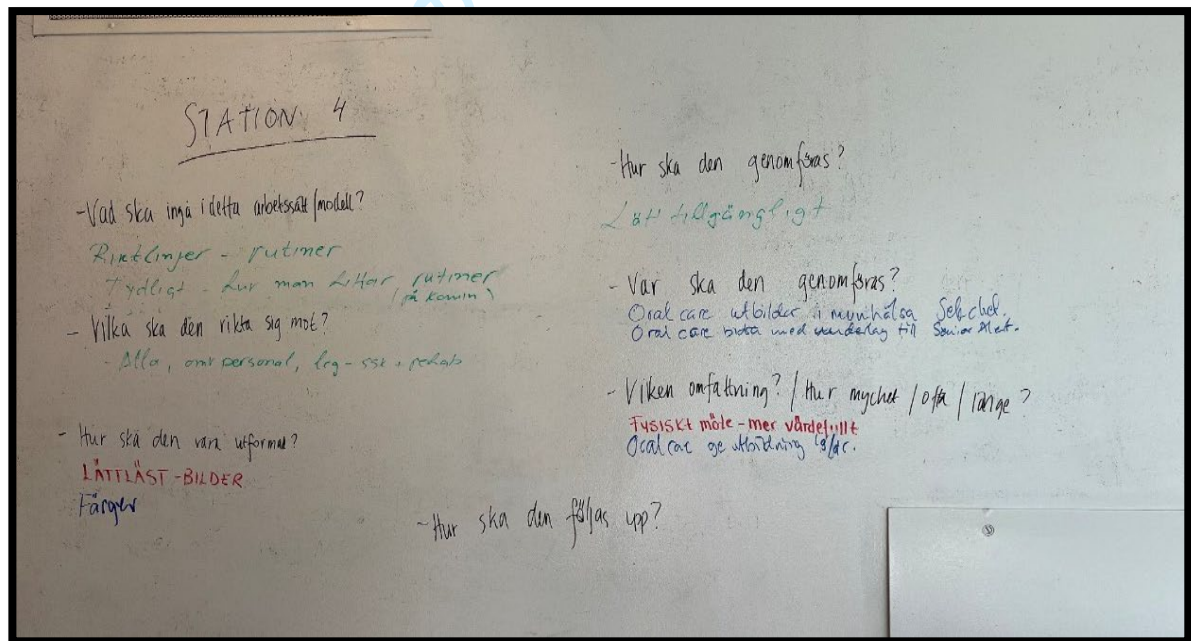
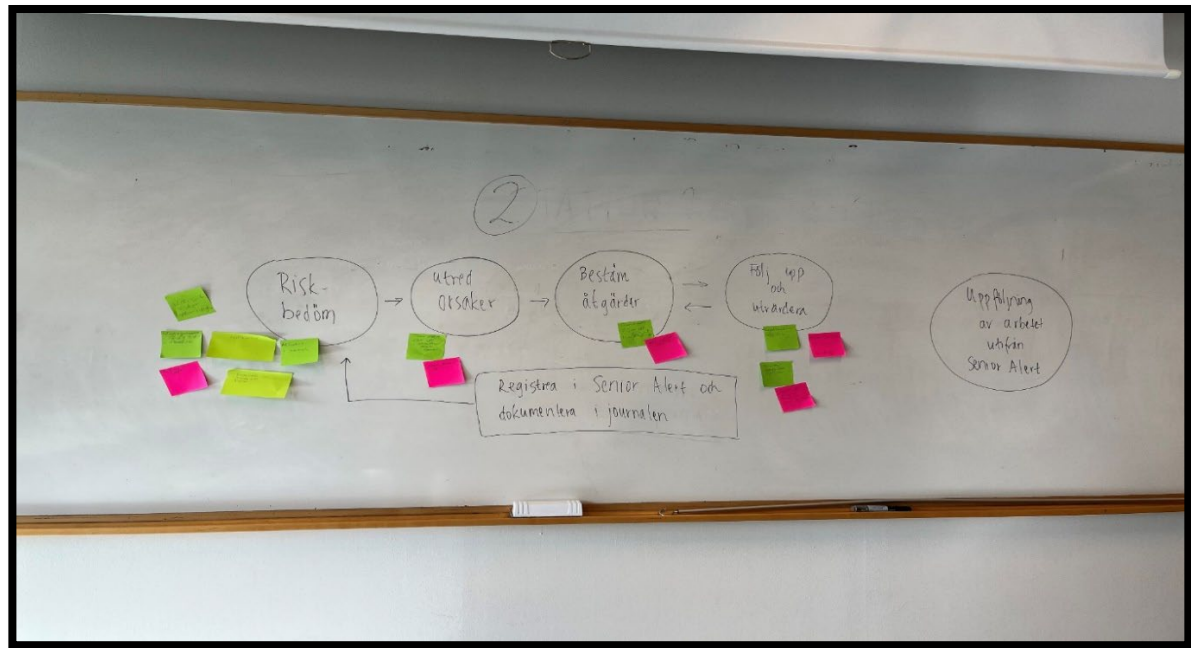


Figure 2. Flowchart of the two-arm pragmatic cluster randomized controlled trial. The flowchart illustrates phase two of the development of the STAIR OF KNOWLEDGE intervention.



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Figure 3. These pictures illustrate the end-users' participation in stations two and four in one of the four workshops.

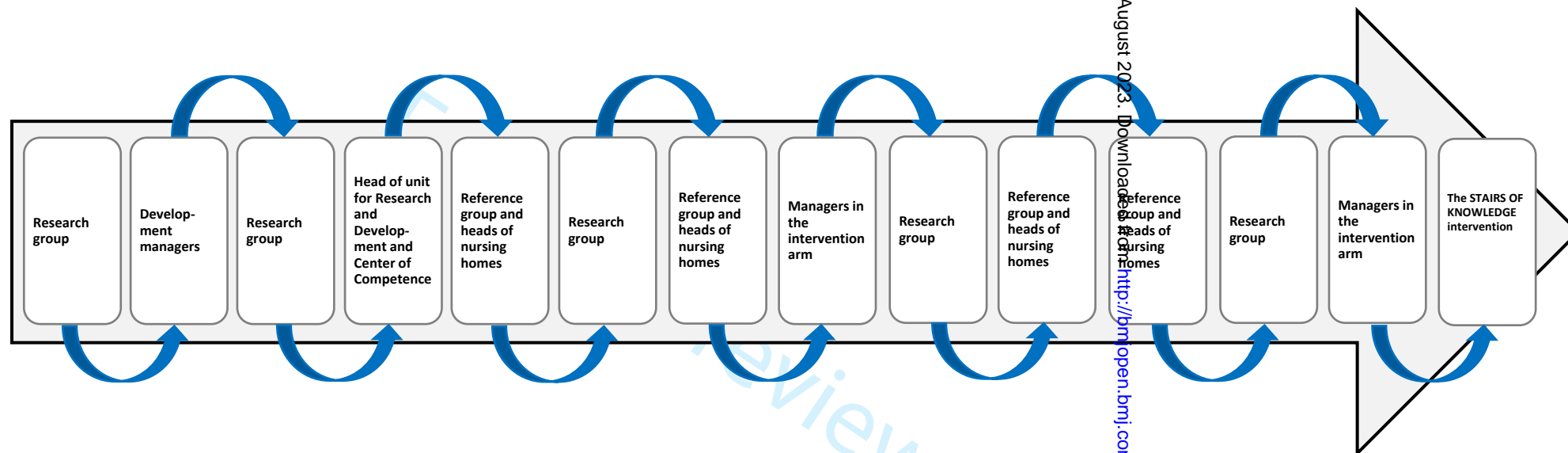
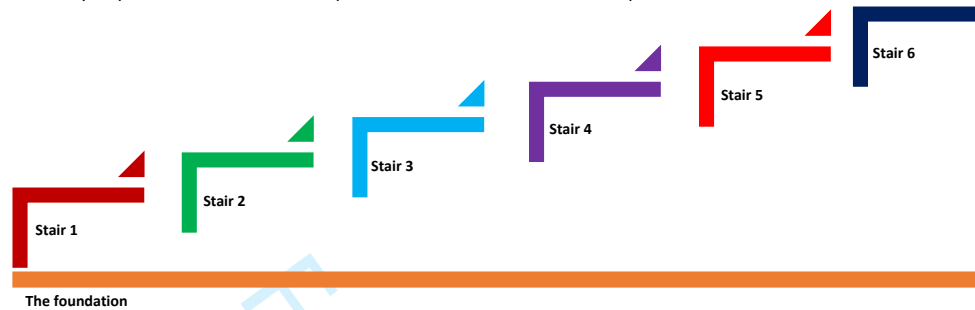


Figure 4. The iterative and dynamic process of designing the final outline of the STAIR OF KNOWLEDGE intervention between April and September 2022, including meetings and discussions with stakeholders. The blue arrows illustrate that adjustments were made following each meeting.

The STAIR OF KNOWLEDGE



The STAIR OF KNOWLEDGE is addressed to all nurse aides, registered nurses and managers who work with older persons in nursing homes. The STAIR OF KNOWLEDGE aims to increase knowledge regarding the preventive care necessary to prevent the risks of falls, pressure ulcers, malnutrition and poor oral health.



The foundation is mandatory for nurse aides, registered nurses and managers. **Stairs 1-4 and stair 6** are mandatory for all nurse aides, registered nurses and managers. **Stair 5** is mandatory for individuals who register in Senior Alert. Follow the instructions below.

For your convenience, click the boxes as you progress through the STAIR OF KNOWLEDGE.

- | | | | |
|------------|--------------------------|------------|--------------------------|
| Foundation | <input type="checkbox"/> | Stair 4a-d | <input type="checkbox"/> |
| Stair 1a-d | <input type="checkbox"/> | Stair 5 | <input type="checkbox"/> |
| Stair 2a-d | <input type="checkbox"/> | Stair 6 | <input type="checkbox"/> |
| Stair 3 | <input type="checkbox"/> | | |

The foundation. Local working description of the entire preventive care working process.

- Link to the local working routine.

Stair 1a-d. General information regarding falls, pressure ulcers, malnutrition and poor oral health.

- Links to texts and videos regarding falls, pressure ulcers, malnutrition and poor oral health.

Stair 2a-d. Risk assessment of falls, pressure ulcers, malnutrition and poor oral health.

- Links to texts and videos regarding the risk assessment of falls, pressure ulcers, malnutrition and poor oral health.

Stair 3. Causes of falls, pressure ulcers, malnutrition and poor oral health.

- Link to text regarding the causes of falls, pressure ulcers, malnutrition and poor oral health.

Stair 4a-d. Preventive care interventions for falls, pressure ulcers, malnutrition and poor oral health.

- Links to texts regarding preventive care interventions for falls, pressure ulcers, malnutrition and poor oral health.

Stair 5. Registering in Senior Alert

- Links to texts and videos regarding how to register in Senior Alert.

Stair 6. Inspiration week

- Inspiration week focuses on preventive care intended to prevent the risks of falls, pressure ulcers, malnutrition and poor oral health in an inspiring and motivating way. The inspiration week will be organized by and for employees and managers. The inspiration week is preferably organized twice per year.

Figure 5. Final design of the STAIR OF KNOWLEDGE intervention.

GUIDED – a guideline for reporting for intervention development studies.

Supplementary File 1: Blank Checklist

Item description	Explanation	Page in manuscript where item is located	Other*
1. Report the context for which the intervention was developed.	Understanding the context in which an intervention was developed informs readers about the suitability and transferability of the intervention to the context in which they are considering evaluating, adapting or using the intervention. Context here can include place, organisational and wider socio-political factors that may influence the development and/or delivery of the intervention (15).	Page 5 (Study context)	
2. Report the purpose of the intervention development process.	Clearly describing the purpose of the intervention specifies what it sets out to achieve. The purpose may be informed by research priorities, for example those identified in systematic reviews, evidence gaps set out in practice guidance such as The National Institute for Health and Care Excellence or specific prioritisation exercises such as those undertaken with patients and practitioners through the James Lind Alliance.	Page 3-4 (Introduction) Page 6-10 Development of the intervention)	
3. Report the target population for the intervention development process.	The target population is the population that will potentially benefit from the intervention – this may include patients, clinicians, and/or members of the public. If the target population is clearly described then readers will be able to understand the relevance of the intervention to their own research or practice. Health inequalities, gender and ethnicity are features of the target population that may be relevant to intervention development processes.	Page 6-10 (Development of the intervention) Page 10 (Results)	
4. Report how any published intervention development approach contributed to the development process	Many formal intervention development approaches exist and are used to guide the intervention development process (e.g. 6Squid (16) or The Person Based Approach to Intervention Development (17)). Where a formal intervention development approach is used, it is helpful to describe the process that was followed, including any deviations. More general approaches to intervention development also exist and have been categorised as follows (3):- Target Population-centred intervention development; evidence and theory-based intervention development; partnership intervention development; implementation-based intervention development; efficacy-based intervention development; step or phased-based intervention development; and intervention-specific intervention development (3). These approaches do not always have specific guidance that describe their use. Nevertheless, it is helpful to give a rich description of how any published approach was operationalised	Page 3-4 (Introduction) Page 5 (Study design)	
5. Report how evidence from different sources informed the intervention development process.	Intervention development is often based on published evidence and/or primary data that has been collected to inform the intervention development process. It is useful to describe and reference all forms of evidence and data that have informed the development of the intervention because evidence bases can change rapidly, and to explain the manner in which the evidence and/or data was used. Understanding what evidence was and was not available at the time of intervention development can help readers to assess transferability to their current situation.	Page 6-10 (Development of the intervention)	
6. Report how/if published theory informed the intervention development process.	Reporting whether and how theory informed the intervention development process aids the reader's understanding of the theoretical rationale that underpins the intervention. Though not mentioned in the e-Delphi or consensus meeting, it became increasingly apparent through the development of our guidance that this theory item could relate to either existing published theory or programme theory	Page 3-4 (Introduction) Page 5 (Study design) Page 6 (Theory)	
7. Report any use of components from an existing intervention in the current intervention development process.	Some interventions are developed with components that have been adopted from existing interventions. Clearly identifying components that have been adopted or adapted and acknowledging their original source helps the reader to understand and distinguish between the novel and adopted components of the new intervention.	The intervention is based on existing evidence-based knowledge in Senior Alert. See figure 5.	
8. Report any guiding principles, people or factors that were prioritised when making decisions during the intervention development process.	Reporting any guiding principles that governed the development of the application helps the reader to understand the authors' reasoning behind the decisions that were made. These could include the examples of particular populations who views are being considered when designing the intervention, the modality that is viewed as being most appropriate, design features considered important for the target population, or the potential for the intervention to be scaled up.	Page 6-10 (Development of the intervention)	

Item description	Explanation	Page in manuscript where item is located	Other*
9. Report how stakeholders contributed to the intervention development process.	Potential stakeholders can include patient and community representatives, local and national policy makers, health care providers and those paying for or commissioning health care. Each of these groups may influence the intervention development process in different ways. Specifying how differing groups of stakeholders contributed to the intervention development process helps the reader to understand how stakeholders were involved and the degree of influence they had on the overall process. Further detail on how to integrate stakeholder contributions within intervention reporting are available (19).	Page 6-10 (Development of the intervention)	
10. Report how the intervention changed in content and format from the start of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	Page 6 (Analysed the data from the focus group interviews and workshops) + Page 7 (Third phase)	
11. Report any changes to interventions required or likely to be required for subgroups.	Specifying any changes that the intervention development team perceive are required for the intervention to be delivered or tailored to specific sub groups enables readers to understand the applicability of the intervention to their target population or context. These changes could include changes to personnel delivering the intervention, to the content of the intervention, or to the mode of delivery of the intervention.	Page 8-9 (Analysed the data from the focus group interviews and workshops) + Page 9 (Third phase) + Page 10 (Results)	
12. Report important uncertainties at the end of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	Page 11-12 (Discussion)	
13. Follow TIDieR guidance when describing the developed intervention.	Interventions have been poorly reported for a number of years. In response to this, internationally recognized guidance has been published to support the high quality reporting of health care? interventions ⁵ and public health interventions ¹⁴ . This guidance should therefore be followed when describing a developed intervention.	The description of the intervention follows TIDieR	
14. Report the intervention development process in an open access format.	Unless reports of intervention development are available people considering using an intervention cannot understand the process that was undertaken and make a judgement about its appropriateness to their context. It also limits cumulative learning about intervention development methodology and observed consequences at later evaluation, translation and implementation stages. Reporting intervention development in an open access (Gold or Green) publishing format increases the accessibility and visibility of intervention development research and makes it more likely to be read and used. Potential platforms for open access publication of intervention development include open access journal publications, freely accessible funder reports or a study web-page that details the intervention development process.	Submitted to the BMJ Open	

*e.g. if item is reported elsewhere, then the location of this information can be stated here.

BMJ Open

The STAIR OF KNOWLEDGE – a codesigned intervention to prevent pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes: development of a complex intervention

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Title

The STAIR OF KNOWLEDGE – a codesigned intervention to prevent pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes: development of a complex intervention

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Abstract

Objectives: To describe the development of a codesigned complex intervention intended to prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes.

Design: A complex intervention development study. The development of the intervention was conducted in three phases. We established contact with stakeholders in the municipality, updated us of current status of the literature in this area and conducted studies in the local context (1). We codesigned the intervention in workshops together with end users (2). We codesigned the final outline of the intervention in an iterative process with stakeholders (3).

Setting: Nursing homes in the municipality in southern Sweden.

Participants: End users (n=16) in nursing homes (n=4) codesigned the intervention together with the research group in workshops (n=4) in March-April 2022. Additionally, stakeholders (n=17) who were considered to play an important role in developing the intervention participated throughout this process. Data were analysed using reflexive thematic analysis.

Results: Four workshops were conducted with end users (n=16) and thirteen meetings with stakeholders (n=12) were held during the development process. The intervention aims to bridge the evidence-practice gap regarding the preventive care process of the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes. The intervention is aimed at end users, lasts for three weeks and is divided into two parts. First, end users obtain knowledge on their own by following written instructions. Second, they meet, interact and discuss the knowledge acquired during part one.

Conclusion: The intervention is robustly developed and thoroughly described. The study highlights the extensive process that is necessary for developing tailored complex interventions. The description of the entire development process may enhance the replicability of this intervention. The intervention needs to be tested and evaluated in an upcoming feasibility study.

Trial number: Clinical Trial NCT05308862.

Strengths

- Inspired by the Medical Research Council guidelines for complex intervention, a robust development process was undertaken based on the literature and research conducted in the local context prior to developing the complex intervention.
- A complex intervention was codesigned both with and for nurse aides, registered nurses and managers in workshops. Additionally, key persons working in the municipality were engaged in the development of this tailored intervention.
- To bridge the evidence-practice gap regarding the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes, knowledge translation strategies were applied during the development process in accordance with the action part of the knowledge-to-action framework.
- A thorough description of the entire development process may enhance the replicability of the current intervention.

Limitations

- One limitation of the development process was that this design is time- and resource-consuming. On the other hand, this was necessary to develop a tailored complex intervention that might enhance the likelihood of successful implementation. The transferability of the tailored intervention to other nursing homes might also be a limitation.

Introduction

There remains an evidence-practice gap in preventing the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes^{1 2}. These health risks cause a major burden for older persons³ and they are costly for the health care system⁴. Since older persons are more vulnerable to these health risks⁵ and considering the increasing ageing population globally, particularly with regard to older persons aged 80 years or older⁶, evidence-based preventive work is crucial to manage this demographic challenge and, importantly, these health risks among older persons.

In Sweden, there is a national quality register, Senior Alert, providing an individualized, standardized, structured and systematic preventive care work process for older persons 65 years or older who are at risk of pressure ulcers, malnutrition, poor oral health and falls⁷. Senior Alert provides evidence-based knowledge aimed at preventing these health risks to enable a healthy ageing among older persons⁸; in addition, it can increase cost efficiency⁹. However, a lack of knowledge among those working with older persons has been identified as one major challenge regarding to preventive work^{2 10}. As a result, these health risks continue to be prevalent⁷. For instance, approximately every third older person living in a nursing home faces at least one of these health risks, and every tenth older person faces all four of these health risks¹. Additionally, not all older persons who are at risk have planned care interventions^{11 12} and there is a mismatch between identified risks and planned and performed care interventions^{13 14}, thus indicating an evidence-practice gap and consequently, highlighting the urgent need of translating knowledge into practice.

Nevertheless, this is not unique to Sweden or this context; in contrast, health systems worldwide face the shared challenge of translating knowledge into practice¹⁵. Knowledge translation has been defined as “*a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve health care of people in the country, provide more effective health service and products and strengthen the health care system*”, p. 165¹⁶. Ineffective knowledge translation can result in an evidence-practice gap¹⁷ and, worryingly, lead to situations in which patients are denied interventions that have been proven to be beneficial¹⁸, which in turn can result in a reduction in their quality of life¹⁹.

To bridge this evidence-practice gap, conceptual frameworks are recommended²⁰. The knowledge-to-action (KTA) framework is intended to help the parties involved in the process of knowledge translation¹⁸. The KTA framework is also appropriate when addressing an evidence-practice gap¹⁵ and conducting pragmatic research¹⁸.

As a part of translating knowledge into practice and promoting knowledge use by end users²¹, the engagement of both researchers and stakeholders in research is crucial²². Engaging stakeholders at an early stage in the development of solutions that can be applied to real world settings is essential according to the Medical Research Council's (MRC) framework for complex interventions²³. Complex interventions have multiple components, target multiple groups or levels of an organization and attempt to affect multiple outcomes²³. Additionally, for complex interventions to be most useful to end users, the local context must be taken into account²⁴. Since it is well underpinned that organizational factors hinder preventive work in nursing homes^{2 25}, considering and understanding the local context and integrating it into the process of intervention development is crucial²⁶.

Consequently, change in the practices of nursing homes is considered to be complex²⁷, but if complex interventions are tailored to the local context²⁸, including the targets of the intervention^{23 24} and is directly relevant to them²⁹, such interventions could be successful.

Aim

The aim of this study was to describe the development of a codesigned complex intervention intended to prevent pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes.

Methods

Definitions

Nursing homes were defined based on the definition provided by Neziraj et al. (2021)¹: older persons receiving municipal health care in residential care homes.

Health care personnel and managers were defined based on the definition provided by Neziraj et al. (2021) as follows²:

Nurse aide: a person with a secondary degree in nursing, involves three years of study in high school *or* a person without any formal education in nursing.

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3 *Registered nurse:* a person with a bachelor's degree in nursing, which involves three years of
4 study at university.
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7 *Manager:* a person who is in charge of nurse aides or registered nurses.
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10 *End users:* nurse aides, registered nurses and managers working in nursing homes.
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12 *Stakeholders:* key persons working in the municipality who are considered to play an
13 important role in the development and implementation of the intervention.
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16 **Study context and setting**

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18 In nursing homes, nurse aides are the main providers of care and services and are on duty
19 around the clock. Nurse aides work under the regulations of the Social and Services Act
20 (SFS)³⁰ but are also delegated tasks according to the Health and Medical Services Act
21 (HSL)³¹, usually by registered nurses. Registered nurses guide care in nursing homes and
22 work under the regulations of HSL³¹. In the current setting, a large town located in southern
23 Sweden with 39 nursing homes, one registered nurse (or occasionally more depending on the
24 size of the nursing home) is located in the nursing home during office hours but is also
25 available at any other time. Managers who are in charge of the care and services provided by
26 the nurse aides are located at their respective nursing homes during office hours.
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30 For transparency, the research group (n=5) positions are reported; four of the researchers hold
31 positions as either doctoral students (MN), associated professors (MAX), professors (CK) or
32 senior lectures (PH) at the affiliated university. The last author (MA) is a PhD and hold the
33 position as a research and development coordinator in the municipality where the study was
34 conducted. All the authors are registered nurses, and two of them (MN, MA) specialize in
35 elderly care and have worked in this context previously,
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39 In addition, a reference group was created, which consisted of experts (n=7) drawn from the
40 local context; nurse aide (n=1), managers in charge of nursing homes (n=2), head of managers
41 in charge of registered nurses (n=1), development managers (n=2) and head of the nursing
42 homes in the municipality (n=1).
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45 **Study design**

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47 The current study was a part of the PROSENIOR program focusing on prevention of pressure
48 ulcers, malnutrition, poor oral health and falls among older persons in nursing homes
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50 [\(PROSENIOR: Prevention of falls, pressure ulcers, malnutrition and poor oral health in older](#)
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3 [persons in Skåne | Malmö University \(mau.se\)](#)). This part of the PROSENIOR program is
4 designed as a two-arm pragmatic cluster randomized trial where the overall aim is to develop,
5 test and evaluate a codesigned complex intervention to prevent pressure ulcers, malnutrition,
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7 poor oral health and falls among older persons living in nursing homes. However, the current
8 study focused on the development of a codesigned complex intervention (hereafter called the
9 intervention). The development of the intervention was conducted in three phases. The phases
10 are described below. The development of the current intervention was conducted in a
11 pragmatic paradigm as it is intended to work in a real-world setting²⁹; this process was
12 inspired by the MRC guidelines for complex interventions²⁴, applied the KTA framework¹⁸
13 and engaged end users and stakeholders in the process of codesign³².

14
15 We follow the guidance for reporting intervention development studies (GUIDED)³³ when
16 describing the development of the intervention and the template for intervention description
17 and replication (TIDieR) checklist and guide³⁴ when describing the intervention. We use
18 “development” to refer to the whole process of intervention development and “design” to
19 indicate the intervention content, format and delivery.

20 21 **Patient and public involvement**

22 Patients or informal caregivers were not involved in the research process. End users
23 codesigned the intervention with the research group in workshops. Stakeholders were also
24 involved in this research; they supported the research group throughout the entire
25 development of the intervention by contributing their valuable knowledge. All engagement is
26 described in detail in the section “Development of the intervention” below.

27 28 **Development of the intervention**

29 We developed the intervention in three phases and applied the KTA framework in all phases
30 (Figure 1).

31 32 *Theory*

33 The KTA framework takes implementation strategies into account already in the development
34 phase¹⁸, which promotes and sustains practice change¹⁵. We applied the KTA framework
35 because it offers a structured and systematic approach to translate knowledge into practice¹⁸.
36 It comprises two parts: knowledge creation and the action cycle. Since evidence-based
37 knowledge is already available to end users in the quality register Senior Alert, the action
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3 cycle was applied during the development of the current intervention. The action cycle
4 consists of the following steps: *1. Identify the problem, identify and review selected*
5 *knowledge, 2. Adapt knowledge to the local context, 3. Assess barriers to knowledge use, 4.*
6 *Select and tailor implementation strategies, 5. Monitor knowledge use, 6. Evaluate the*
7 *outcomes and 7. Sustain knowledge use*^{18 35}. Steps 1-4 the action cycle were applied
8 throughout the development process of developing the intervention in an iterative, dynamic
9 and permeable way.

15 ***Phase one***

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18 During this phase, we established contact with stakeholders in the municipality, updated us
19 the of current status of the literature in this area and conducted studies in the local context.

21 *Establishing contact with stakeholders in the municipality*

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24 Initially, we established contact and met with the head of the nursing homes in the
25 municipality. The reference group was created in this phase (described in the paragraph
26 “Study context and setting” above).

29 *Searching for literature and conducting studies in the local context*

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32 As a part of step 1 in the KTA framework, *identify the problem, identify and review selected*
33 *knowledge*, firstly, we updated us of current status of the literature regarding prevention of
34 pressure ulcers, malnutrition, poor oral health and falls and intervention studies in this area.
35 Subsequently, we conducted a cross-sectional study to determine the prevalence of the risks
36 of pressure ulcers, malnutrition, poor oral health and falls in nursing homes in southern
37 Sweden¹.

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40 As a part of steps 2-3 in the KTA framework, *adapt knowledge to the local context and assess*
41 *barriers to knowledge use*, we conducted focus group interviews (n=5) with end users (n=21)
42 who worked in nursing homes to prevent pressure ulcers, malnutrition, poor oral health and
43 falls². The focus group interviews lasted between 63 and 106 min (mean 83 min). A detailed
44 description of this study and its participants is provided in Neziraj et al². Additionally, we
45 asked the end users included in our previous study, i.e., Neziraj et al², how an optimal
46 intervention could be designed to prevent the risks of pressure ulcers, malnutrition, poor oral
47 health and falls among older persons in nursing homes. These particular data were targeted for
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3 the current study. Hence, these data were not reported in our previous study, but are included,
4 analysed and reported in our current study.
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7 Phase one suggested that individuals working with older persons in nursing homes need
8 increased knowledge concerning how to prevent these health risks. Since existing evidence
9 and knowledge concerning how to prevent these health risks is already contained in Senior
10 Alert, the challenge seems to lie in the evidence-practice gap, which highlights the need for
11 support to be provided to end users with regard to translating evidence into practice^{1 2}.
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16 *Phase two*

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18 During this phase, we recruited and randomized nursing homes. Subsequently, we invited end
19 users in the intervention arm to participate in workshops, and planned and conducted the
20 workshops. We also analysed the specific data regarding intervention design drawn from the
21 focus group interviews (see the previous paragraph on phase one for clarification) and the
22 workshops.
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28 *Recruiting and randomizing nursing homes*

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30 For the current study's purpose, randomization was only conducted to invite end users in
31 nursing homes allocated to the intervention arm to codesign an intervention together with the
32 research group in workshops (Figure 2). The nursing home is the cluster and the unit of
33 allocation. Due to the nature of the design, the cluster randomization of nursing homes was
34 unblinded. The randomization procedure will be further reported in detail in an upcoming
35 feasibility study.
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41 Inclusion criteria for the study were nursing homes working with and registered in the quality
42 register Senior Alert. We recruited eligible nursing homes (n=21) to participate in the study
43 via digital meetings. In total, eight nursing homes agreed to participate and were cluster
44 randomized using a computerized program to either the intervention (n=4) or control arm
45 (n=4). Subsequently, we invited end users (n=118) working in nursing homes in the
46 intervention arm to participate in workshops intended to develop a tailored intervention
47 together with the research group; the invitations were extended both via a digital information
48 video and in written form. The remaining end users (n=184) working in the nursing homes
49 who were allocated to the control arm continued with their usual care routine.
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57 *Conducting workshops*

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3 As a part of steps 2-4 in the KTA framework, *adapt knowledge to the local context, assess*
4 *barriers to knowledge use and select and tailor implementation strategies*, we conducted
5 workshops with end users. In total, four workshops were conducted, which featured two nurse
6 aides, one registered nurse and one manager in each workshop; the workshops were
7 conducted over the course of four weeks (March-April 2022). The workshops were kept small
8 to offer the end users the possibility of exhibiting activity and creativity³⁶. The first author
9 (MN) led the workshops together with one of the coauthors (all coauthors participated in one
10 workshop each). The workshops were intended to serve as a place in which participants could
11 learn together and discuss the design of the intervention in four different stations (Table 1).
12 The end users engaged in active discussion and wrote creative ideas and suggestions on the
13 walls and the board in a lecture hall designed for the purpose of encouraging creative
14 pedagogy (Figure 3). In the first station, the end users were asked to discuss the risks of
15 pressure ulcers, malnutrition, poor oral health and falls and the care interventions that should
16 be applied. In the second station, they were asked to discuss and identify barriers and
17 facilitators they had encountered in their own work regarding the preventive care process
18 stipulated by Senior Alert (identify a risk, assess causes and plan, undertake and evaluate care
19 intervention). Barriers were written down on pink post-it notes, while facilitators were written
20 down on green post-it notes. These post-it notes were subsequently placed at the appropriate
21 location on the board with regard to the predawn preventive care process. The focus of the
22 discussions at station three was on the end users' needs and the support they needed
23 throughout the preventive care process. In the fourth station, they were asked to discuss the
24 core components of the intervention, how to provide follow-ups and implementation
25 strategies. After completing each workshop, MN photographed and briefly summarized the
26 written data from each station. This summary was used if the end users in the subsequent
27 workshop reached an impasse and/or discussed and wrote similar suggestions and ideas to
28 those proposed by the end users in the previous workshop. Each workshop lasted for three
29 hours, and the discussions were audio recorded to support the written data collection during
30 the analysis.
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Table 1. Workshop content (n=4).

Workshop	Station	Content	Examples of questions to discuss
Workshop 1-4	Station 1	Case regarding an older person at risk of pressure ulcers, malnutrition, poor oral health and falls living in a nursing home	<ul style="list-style-type: none"> • What would you have done in this case regarding these four risks? • Are there any good examples? What can you learn from good examples? • What additional knowledge do you need regarding these four risks in order to produce a risk assessment and provide adequate care interventions?
	Station 2	Senior Alert's care process	<ul style="list-style-type: none"> • Place green/pink post-it notes on the care process regarding what works/what can be improved in your own work and workplace.
	Station 3	End users needs' and the support they need regarding preventive work	<ul style="list-style-type: none"> • What do you need in your preventive work? • Why is this important, and what is most important (rank 1-3)? • Who needs help in the context of preventive work? • Who should be involved and in what way? • What is necessary for it to be feasible? • How can you work better/smarter? • How can you work in a more sustainable way?
	Station 4	Core components of the intervention	<ul style="list-style-type: none"> • What should be included in the intervention? • Who should it target? • How should it be designed? • How much/often/for how long should the intervention take place? • How should it be followed up? • Where should it be implemented? • How should it be implemented?

Analysing the data from the focus group interviews and the workshops

The analysis was guided by the six phases of reflexive thematic analysis described by Braun and Clarke^{37 38}: 1. *Familiarizing with the data*, 2. *Coding*, 3. *Generating initial themes*, 4. *Reviewing the identified themes*, 5. *Defining and naming the themes* and 6. *Producing the report*. Thematic analysis was chosen because it facilitates a flexible analysis process but simultaneously provides researchers with the core skills they need to conduct the analysis.

To familiarize ourselves with the data, MN and MA read the transcripts from the focus group interviews, including the data specifically collected for the current study, and the written data collected from the workshops. In addition, MN listened to all the audio-recorded discussions from the workshops meticulously. During the process of reading the data, MN and MA reflected on and generated initial codes. Subsequently, MN and MA met and discussed these initial codes (1). Thereafter, MN and MA separately engaged in a process of identifying and coding entities of interest in relation to the design of the intervention, giving equal attention to all the data (2). The initial codes were then sorted into their core components in relation to the design of the intervention (3). Next, the core components were reviewed by MN to determine whether any relevant data regarding the design of the intervention had been missed (4). Subsequently, MN designed an outline of the intervention. This outline contained the intervention's proposed design, including its content, format, plan for delivery and duration. In the following step of the analysis, the entire research group met and discussed the design of the outline of the intervention. During this step, MN continuously revised the outline of the intervention following discussions within the research group (5). Then, the outline of the intervention was redesigned by MN. The redesigned outline of the intervention was then presented to the research group before it was presented to the stakeholders. The process of producing the final design of the intervention is described in phase three below (6).

Phase three

As part of steps 2-4 in the KTA framework, *adapt knowledge to the local context, assess barriers to knowledge use and select and tailor implementation strategies*, MN and MA met regularly with stakeholders in structured meetings to present and discuss the outline of the intervention. MN documented all the meetings. MA works within the municipality and thus facilitated contact with stakeholders who were considered to play an important role in this part of designing the intervention. Since this part of the process was dynamic and iterative and because all relevant uncertainties had not been addressed in the redesigned outline of the

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3 intervention, it was helpful to meet stakeholders for the purpose of identifying and addressing
4 the remaining uncertainties regarding the content, format, delivery and duration of the
5 intervention. This part of the process was time-consuming and required a back-and-forth
6 process involving meetings and discussions between MN and MA, within the entire research
7 group and with the stakeholders. Next, the redesigned outline of the intervention was adjusted
8 by MN in accordance with the results of these meetings and discussions (Figure 4). Finally,
9 MN investigated whether any data from the focus group interviews and the workshops had
10 been missed, since these data were intended to serve as the foundation for designing the final
11 outline of the intervention. The final design of the intervention, the STAIR OF
12 KNOWLEDGE (Figure 5), is described below.

21 Results

22
23 A majority of the end users (n=16) in workshops (n=4) were women (n=13), between the ages
24 of 28-63 years (mean 53), and had worked for 3-41 years (mean 18). The meetings (n=13)
25 with stakeholders (n=12) lasted between 60-180 min (mean 134 min).

29 The final design of the intervention

30
31 The final design of the intervention was described in line with the TIDieR checklist³⁴
32 (Supplementary file).

33
34 The STAIR OF KNOWLEDGE consists of *the foundation and stairs 1-6*, lasts for three
35 weeks and is divided into two parts. Part one, including *the foundation and stairs 1-5*, takes
36 place throughout the entire intervention period (weeks 1-3) and is delivered digitally to end
37 users in the nursing homes via their workplace email addresses. Part two includes *stair 6* and
38 takes place during the last week of the intervention period (week 3) in the nursing homes in
39 question (Figure 5).

46 The content of the intervention

47 *Part one of the intervention: the foundation and stairs 1-5*

48
49 End users emphasized uncertainties of different professionals' responsibilities regarding the
50 preventive work. For instance, they highlighted that it is highly relevant for respective
51 professional to know "who does what" regarding the preventive working. Hence, *the*
52 *foundation* is intended to facilitate for different professionals regarding responsibilities for
53 respective profession and working routine in the local context. *The foundation* provide end
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3 users with knowledge and awareness of how to work preventively in the context of an existing
4 local working routine and is intended to represent “the ground to stand on”.

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7 Furthermore, end users expressed a need of increased knowledge regarding the health risks
8 and the entire preventive working process. They stressed the importance of basic knowledge
9 when working with older persons in nursing homes. According to end users, not all of them
10 has basic knowledge in how to prevent these health risks among older persons. This was
11 particularly common among temporary workers. To meet their need, *stairs 1-4* provide the
12 end users with general knowledge about risks of pressure ulcers, malnutrition, poor oral health
13 and falls according to the care process suggested by the quality register Senior Alert (*stair 1*),
14 risk assessment instruments (*stair 2*), the underlying causes of these risks (*stair 3*) and
15 preventive care interventions (*stair 4*). *Stairs 1-5* provide end users with website links that
16 allow them to both read texts and watch videos. *Stairs 1-4* are mandatory for all professionals.
17 *Stair 5* provides end users with knowledge of how to register in the quality register Senior
18 Alert and is mandatory only for users who have access to and the responsibility to register in
19 the quality register Senior Alert.

20 21 22 *Part two of the intervention: stair 6*

23 Although it was necessary for end users to increase their knowledge on their own regarding
24 the preventive work, they particularly highlighted the importance of physical meetings. This
25 was also stressed as important by stakeholders and was considered as a complement to the
26 first part of the intervention. Therefore, in part two, *stair 6*, a facilitator (MN) meets with end
27 users to interact with them and discuss the knowledge acquired during part one. The meetings
28 will be structured including discussions based on different cases related to pressure ulcers,
29 malnutrition, poor oral health and falls. End users will also perform risk assessments, identify
30 the underlying causes and plan accurate care interventions based on these cases. Additionally,
31 end users will identify environmental risk factors related to the risks of pressure ulcers,
32 malnutrition, poor oral health and falls in their own workplace. They will also discuss and
33 generate ideas how to follow up on the preventive care process on an organizational level.
34 This part of the intervention is intended to inspire end users to prevent pressure ulcers,
35 malnutrition, poor oral health and falls among older persons in nursing homes.

36 37 38 **The format of the intervention**

39 40 41 *Part one of the intervention: the foundation and stairs 1-5*

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3 From end users' perspective, it was important with a clear format. They expressed a need of a
4 structured, readable and colourful working "manual". Hence, the format of the intervention is
5 designed as colourful stair with the intention to visualize the entire preventive working
6 process. To enhance the structure, end users are provided with written instructions in
7
8 respective stair. Furthermore, stakeholder emphasized the need of a "self-check box" for end
9
10 users when completing the foundation and stairs in the intervention. Stakeholder believed that
11
12 this could increase participation and involvement among end users. Since both end users and
13
14 stakeholders stressed that there are many end users that do not have the Swedish language as
15
16 their native language, the language is adjusted to suit the local context. Furthermore, end users
17
18 expressed that the format of the intervention should consider different ways of learning. This
19
20 was also highlighted as important by stakeholders. Hence, the format consist of both reading
21
22 texts and watching videos. Moreover, end users and stakeholders emphasized that a digital
23
24 intervention could be a sustainable solution.

25
26 *Part two of the intervention: stair 6*

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28 End users and stakeholder were in agreement that it is necessary to meet and discuss.
29
30 Therefore, in part two of the intervention, end users meet in their respective nursing home.
31
32 Also, the format of this part of the intervention was designed as an inspiration to raise
33
34 awareness of the preventive work among end users.

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36 **The delivery of the intervention**

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38 *Part one of the intervention: the foundation and stairs 1-5*

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40 The intervention will be delivered via email to managers in nursing homes. Subsequently,
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42 respective manager will forward the intervention via workplace email addresses to nurse aides
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44 and registered nurses. The end users highlighted that some learn better individually while
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46 others learn better in group. Therefore, they are permitted to choose if they want to read texts
47
48 and watch videos individually and/or in group. *The foundation and stairs 1-5* is anticipated to
49
50 take approximately 10 minutes, 60 minutes, 20 minutes, 10 minutes, 30 minutes and 60
51
52 minutes respectively for end users to complete. End users can choose to complete this part of
53
54 intervention at once or divide it during working hours.

55
56 *Part two of the intervention: stair 6*

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2
3 Part two of the intervention will be delivered by a facilitator (MN) who will moderate
4 sessions lasting approximately 30 minutes each, Monday-Friday, in the nursing homes in
5 question. If end users participate in all the sessions during this week, the planned amount of
6 time is two and half hours for each end user.
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10 **Discussion**

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12 The current codesigned complex intervention, the STAIR OF KNOWLEDGE, was developed
13 together with end users in workshops in an active and creative way. Stakeholders were also
14 engaged in an iterative and dynamic way throughout the development of the intervention, as
15 an important part of undertaking implementation strategies already in the development
16 phase³⁹. As recommended by the MRC framework²⁴, we meticulously considered the
17 relationship between the intervention and its context when developing the intervention.
18 Furthermore, we followed the strategies for knowledge translation included in the KTA
19 framework¹⁸. Hence, the strengths exhibited by the development of this complex intervention
20 lie in the fact that it was developed both together with and for end users and engaged
21 stakeholders who are considered to play an important role in the development and
22 implementation process. The current intervention is intended to work in a real-world setting
23 and aims to bridge the evidence-practice gap regarding the process of preventing the risks of
24 pressure ulcers, malnutrition, poor oral health and falls; ultimately, this intervention may
25 reduce these risks among older persons in nursing homes.
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37 When developing new intervention, the value of the used design process cannot be
38 understated⁴⁰. In fact, engagement of end users in a creative environment have been linked to
39 more robust research and development efforts, which in turn may drive more successful
40 interventions outcome⁴⁰. Hence, the benefits of codesign are potentially substantial⁴¹. For
41 instance, engaging end users and stakeholders as design partners to the research group could
42 ensure that the intervention exhibits a better fit to their needs³². Engaging end users and
43 stakeholders early enables their experiences and requirements to be taken into account at the
44 start rather than a situation in which the researchers presume to know what is required³⁹. In
45 the current development process, although end users' and stakeholders' engagement ranged in
46 intensity from relatively passive to highly active, their engagement pervaded the entire
47 development process, and important decisions regarding the intervention design were made
48 by considering their input. Furthermore, because we engaged end users and stakeholders, the
49 current intervention was based on their own experiences regarding the evidence and
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3 knowledge that are necessary throughout the entire process of preventing the risks of pressure
4 ulcers, malnutrition, poor oral health and falls. Engaging end users and stakeholders during
5 the developing process⁴² was also important in light of the local context since this enabled us
6 to identify facilitators and barriers in the environment in which the intervention will
7 eventually be implemented²⁶.
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12 A recent scoping review investigating education interventions for health professionals on fall
13 prevention in health care settings⁴³, highlighted that health professional education to prevent
14 fall is important. Nevertheless, the scoping review concluded that there are no uniform
15 education design principles utilized to date⁴³. Another review found that it was uncertain
16 whether education delivered in different format such as didactic or video-based format makes
17 a difference to health professionals' knowledge of pressure ulcers prevention. However,
18 education format in the current developed intervention was designed to fit end users' needs
19 and suit the local context, which may have benefits for the outcome.
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27 Considering and understanding the local context is also crucial when addressing an evidence-
28 practice gap²⁴. In this case, knowledge concerning the process of preventing the risks of
29 pressure ulcers, malnutrition, poor oral health and falls is already contained in the quality
30 register Senior Alert, but this evidence has not been fully translated into practice. Thus, we
31 focused on translating the existing knowledge contained in Senior Alert into practice.
32 However, if this knowledge is to be implemented effectively⁴⁴, it is crucial to employ a
33 conceptual framework²⁰. Therefore, we chose the KTA framework because it provided us
34 with knowledge translation strategies to reduce the evidence-practice gap¹⁸, and it was
35 suitable since the quality register Senior Alert is already in use. Furthermore, adapting
36 knowledge to the local context and assessing barriers to knowledge may enable the
37 research to have a greater impact⁴⁵, which could in turn reduce the evidence-practice gap.
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47 Successful intervention development is characterized as rigorous and scientific and leads to an
48 intervention that can be implemented in a real-world setting³³. The robust research process
49 used to develop the STAIR OF KNOWLEDGE intervention incorporates existing evidence,
50 the views of end users and stakeholders⁴¹, the local context and knowledge translation
51 strategies. Consequently, the use of knowledge translation strategies and the engagement of
52 end users who are embedded in the local context in the development of a tailored complex
53 intervention both for and with them could contribute to increased knowledge and awareness
54 of the entire process of preventive care. This may, in turn, reduce the evidence-practice gap
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3 among end users and, importantly, reduce the risk of pressure ulcers, malnutrition, poor oral
4 health and falls among older persons in nursing homes. Furthermore, the engagement of
5 stakeholders already in the development process is likely to facilitate the implementation of
6 the current intervention.
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10 **Limitations**

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13 Although the development of this complex intervention has been completed, it is important to
14 acknowledge the limitations of the development process. First, only four clusters were
15 included in the development process. Nevertheless, since this part of the trial focused on the
16 development of an intervention rather than its evaluation and because the clusters were
17 recruited pragmatically, the clusters included in the trial could be considered sufficient.
18
19 Second, although all end users in the intervention arm (n=118) were invited to participate in
20 workshops, only 16 participated. However, different professionals participated in the
21 workshops, and the discussions were energetic, active and creative. Third, although this
22 design is creative and can generate new ideas, it is time- and resource-consuming for all parties
23 involved. It requires end users and stakeholders to set aside time and expend extra effort in
24 their daily work. For researchers, this process requires careful planning to enable them to
25 coordinate, meet with many different persons repeatedly and be responsive to all parties
26 involved. However, although this design required the expenditure of time and resources, the
27 engagement of end users, stakeholders and researchers is meaningful and necessary to
28 develop successful interventions; ultimately, this design might have an impact on to prevent
29 the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in
30 nursing homes. Furthermore, the current intervention might offer value when used by others
31 and could likely be adjusted to and tested in similar contexts.
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45 **Conclusion**

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47 The current codesign complex intervention, the STAIR OF KNOWLEDGE, which aims to
48 prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among older
49 persons in nursing homes, is robustly developed and thoroughly described. A careful
50 description of the entire development process and the intervention itself can enhance the
51 replicability of the current intervention. This article highlights the extensive process that is
52 necessary for the development of tailored complex interventions. Finally, this codesigned
53 complex intervention might result in more evidence-based practice concerning the entire
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3 process of preventing the risks of pressure ulcers, malnutrition, poor oral health and falls and,
4 importantly, reduce these health risks among older persons in nursing homes. However,
5 uncertainties regarding the intervention itself remain. Thus, the STAIR OF KNOWLEDGE
6 must be tested and evaluated in an upcoming feasibility study before we continue to the stage
7 of conducting a full trial evaluation.
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11 **Ethical considerations**

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15 This trial was approved by the Swedish Ethical Review Authority (DNR 2019-06414). In
16 addition, written approval was requested and granted by the head of the department of elderly
17 care homes in the municipality in which this trial was conducted. All end users working in
18 eligible nursing homes were invited to participate in the workshops. Moreover, end users had
19 the right to withdraw from participation at any stage without providing reasons and bearing
20 any consequences. Participation in the workshops was based on written consent. The results
21 of this trial may be considered to contribute to scientific value on good ethical grounds, and
22 the benefits of participating in the trial outweigh the corresponding risks.
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29 **Funding statement**

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31 This research received financial support with regard to conducting the workshops from the
32 Derbrings and Stöltens research and development foundation. The funders had no role in the
33 research manuscript's design, conduct, analysis, interpretation or drafting.
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37 **CRediT authorship contribution statement**

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40 **Merita Neziraj:** Conceptualization, Methodology, Investigation, Writing – original draft,
41 Writing – review & editing, Validation, Formal analysis, Visualization. **Malin Axelsson:**
42 Conceptualization, Methodology, Investigation, Writing – review & editing, Validation,
43 Supervision. **Christine Kumlien:** Conceptualization, Methodology, Investigation, Writing –
44 review & editing, Validation, Supervision. **Peter Hellman:** Conceptualization, Methodology,
45 Investigation, Writing – review & editing, Validation, Supervision. **Magdalena Andersson:**
46 Conceptualization, Methodology, Investigation, Writing – review & editing, Validation,
47 Formal analysis, Supervision. All the authors read and approved the final version of the
48 manuscript.
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55 **Competing interests**

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58 The authors have no conflicts of interest.
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Participant consent

All participation in the workshops was based on written consent.

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Data sharing statement

The data that support the development of the STAIR OF KNOWLEDGE intervention are not publicly available to ensure confidentiality. All data relevant to the development are included in the article. All figures and tables included in this article are original.

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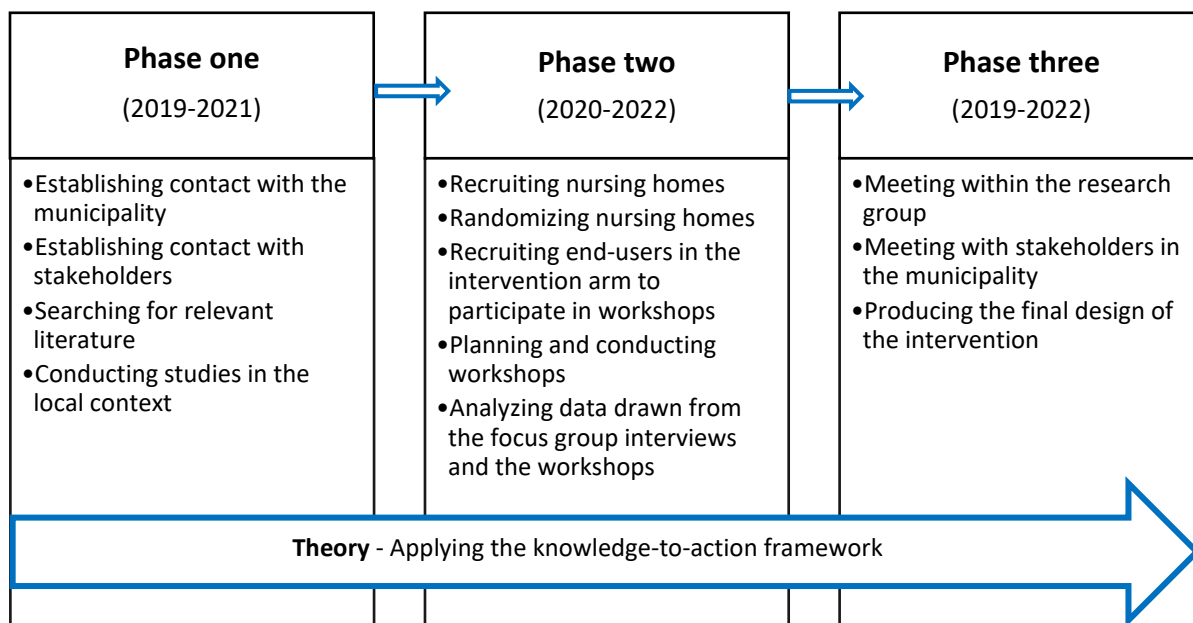


Figure 1. Phases one-three illustrate the process of developing the STAIR OF KNOWLEDGE intervention, which took place between 2019 and 2022. Although the knowledge-to-action (KTA) framework is viewed as a cycle by Graham and colleagues (2006), in this figure, the arrow illustrates the fact that the KTA framework was applied throughout phases one-three of the development process. The KTA framework was applied in an iterative and dynamic way in each phase and is described in detail in the text.

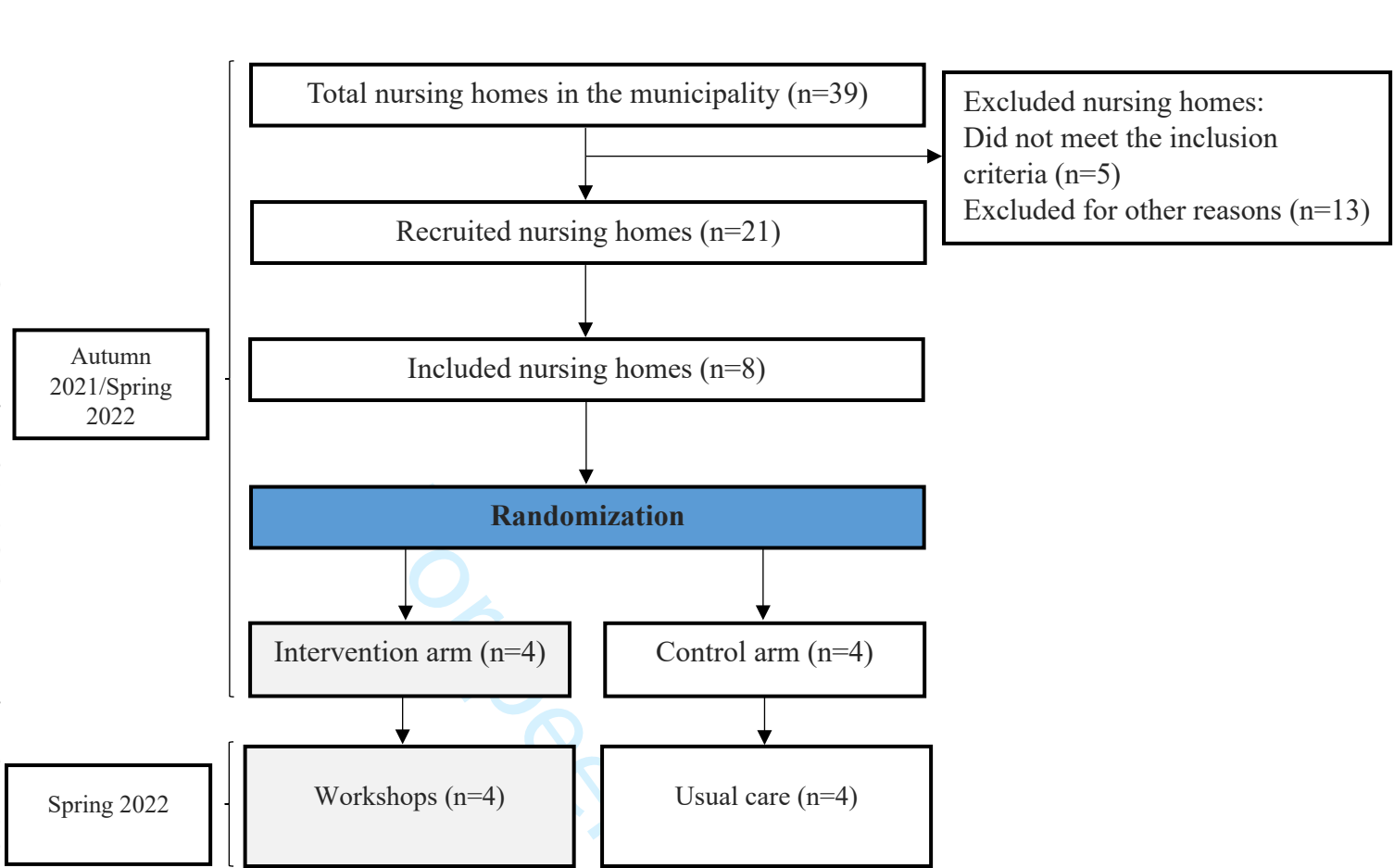
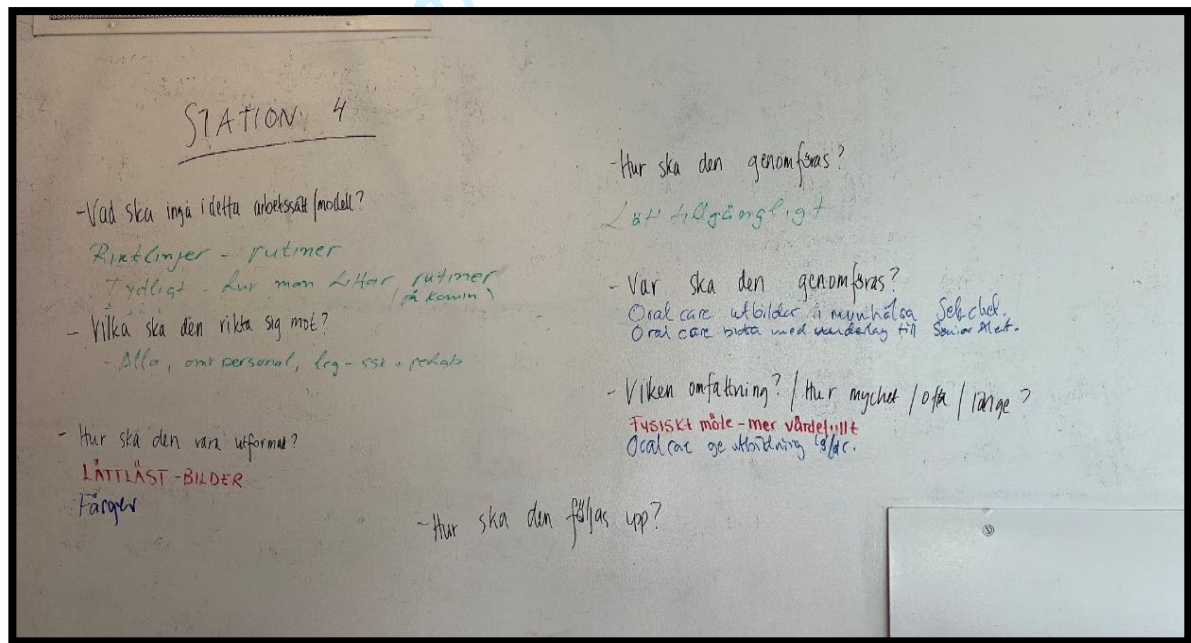
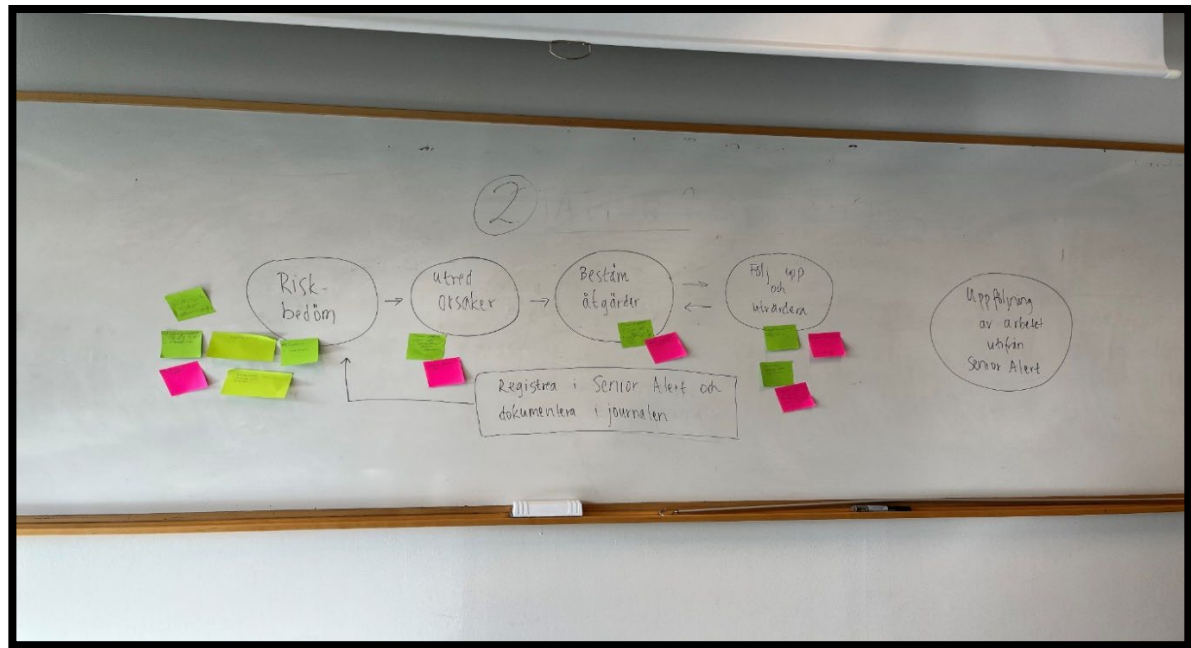


Figure 2. Flowchart of the two-arm pragmatic cluster randomized controlled trial. The flowchart illustrates phase two of the development of the STAIR OF KNOWLEDGE intervention.



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Figure 3. These pictures illustrate the end-users' participation in stations two and four in one of the four workshops.

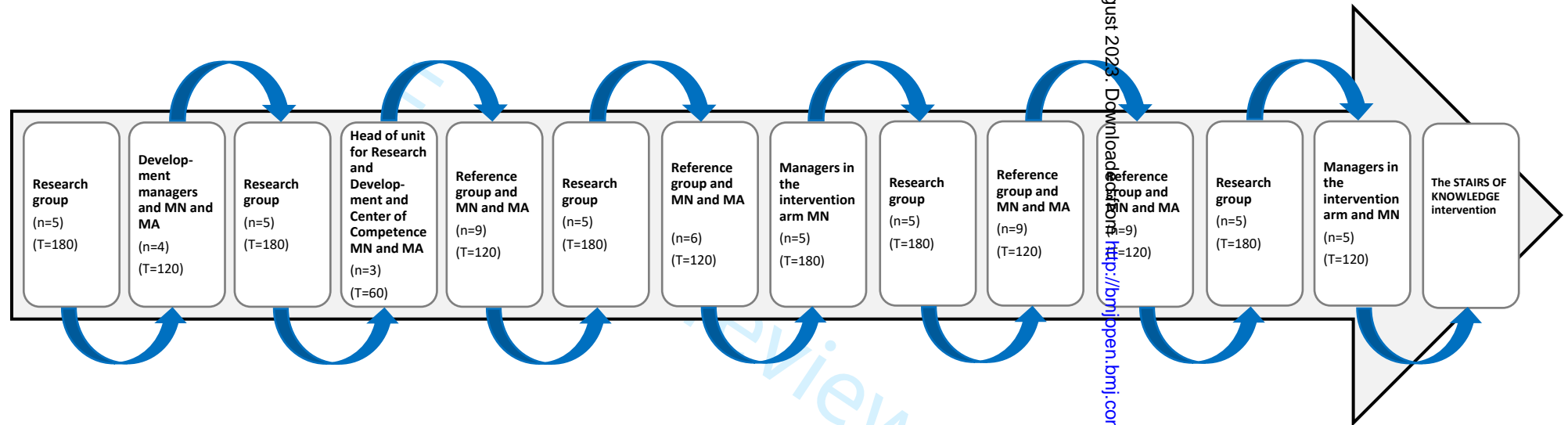
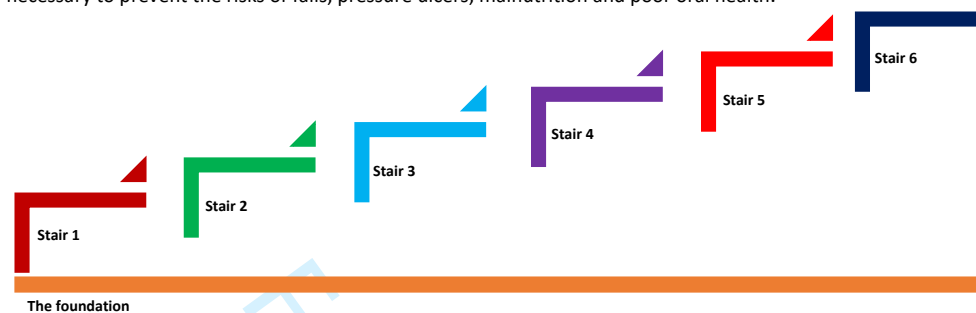


Figure 4. Note: T=how long the meeting lasted for, reported in minutes. MN=the first author. MA=the last author. The iterative and dynamic process of designing the final outline of the STAIRS OF KNOWLEDGE intervention between April and September 2022, including meetings and discussions with stakeholders. In all the meetings, the first author participated. In addition, in some meetings also the last author participated. The blue arrows illustrate that adjustments were made following each meeting.

The STAIR OF KNOWLEDGE



The STAIR OF KNOWLEDGE is addressed to all nurse aides, registered nurses and managers who work with older persons in nursing homes. The STAIR OF KNOWLEDGE aims to increase knowledge regarding the preventive care necessary to prevent the risks of falls, pressure ulcers, malnutrition and poor oral health.



The foundation is mandatory for nurse aides, registered nurses and managers. **Stairs 1-4 and stair 6** are mandatory for all nurse aides, registered nurses and managers. **Stair 5** is mandatory for individuals who register in Senior Alert. Follow the instructions below.

For your convenience, click the boxes as you progress through the STAIR OF KNOWLEDGE.

Foundation	<input type="checkbox"/>	Stair 4a-d	<input type="checkbox"/>
Stair 1a-d	<input type="checkbox"/>	Stair 5	<input type="checkbox"/>
Stair 2a-d	<input type="checkbox"/>	Stair 6	<input type="checkbox"/>
Stair 3	<input type="checkbox"/>		

The foundation. Local working description of the entire preventive care working process.

- Link to the local working routine.

Stair 1a-d. General information regarding falls, pressure ulcers, malnutrition and poor oral health.

- Links to texts and videos regarding falls, pressure ulcers, malnutrition and poor oral health.

Stair 2a-d. Risk assessment of falls, pressure ulcers, malnutrition and poor oral health.

- Links to texts and videos regarding the risk assessment of falls, pressure ulcers, malnutrition and poor oral health.

Stair 3. Causes of falls, pressure ulcers, malnutrition and poor oral health.

- Link to text regarding the causes of falls, pressure ulcers, malnutrition and poor oral health.

Stair 4a-d. Preventive care interventions for falls, pressure ulcers, malnutrition and poor oral health.

- Links to texts regarding preventive care interventions for falls, pressure ulcers, malnutrition and poor oral health.

Stair 5. Registering in Senior Alert.

- Links to texts and videos regarding how to register in Senior Alert.

Stair 6. Inspiration week.

- Inspiration week focuses on preventive care intended to prevent the risks of falls, pressure ulcers, malnutrition and poor oral health in an inspiring and motivating way. The inspiration week will be organized by and for employees and managers. The inspiration week is preferably organized twice per year.

Figure 5. Final design of the STAIR OF KNOWLEDGE intervention.



The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
	The codesigned STAIR OF KNOWLEDGE intervention to prevent pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes: a complex intervention development study	Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	_____	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	4-5 + 7 _____	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	13-15 _____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	13-15 _____	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	5-6 + 13 + _____	_____
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	13-15 _____	_____
	WHERE		

1	7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	13-15	_____
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5		WHEN and HOW MUCH		
6	8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	13-15	_____
7				
8				
9		TAILORING		
10	9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	15	_____
11				
12		MODIFICATIONS		
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14				
15	10.*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	_____
16				
17				
18		HOW WELL		
19				
20	11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	N/A	_____
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23	12.*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	N/A	_____
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** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement**. When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013**

1 **Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see
2 www.equator-network.org).
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GUIDED – a guideline for reporting for intervention development studies.

Supplementary File 1: Blank Checklist

Item description	Explanation	Page in manuscript where item is located	Other*
1. Report the context for which the intervention was developed.	Understanding the context in which an intervention was developed informs readers about the suitability and transferability of the intervention to the context in which they are considering evaluating, adapting or using the intervention. Context here can include place, organisational and wider socio-political factors that may influence the development and/or delivery of the intervention (15).	Page 6 (Study context and setting)	
2. Report the purpose of the intervention development process.	Clearly describing the purpose of the intervention specifies what it sets out to achieve. The purpose may be informed by research priorities, for example those identified in systematic reviews, evidence gaps set out in practice guidance such as The National Institute for Health and Care Excellence or specific prioritisation exercises such as those undertaken with patients and practitioners through the James Lind Alliance.	Page 4-5 (Introduction) Page 7-13 Development of the intervention)	
3. Report the target population for the intervention development process.	The target population is the population that will potentially benefit from the intervention – this may include patients, clinicians, and/or members of the public. If the target population is clearly described then readers will be able to understand the relevance of the intervention to their own research or practice. Health inequalities, gender and ethnicity are features of the target population that may be relevant to intervention development processes.	Page 7-13 (Development of the intervention) Page 13-16 (Results)	
4. Report how any published intervention development approach contributed to the development process	Many formal intervention development approaches exist and are used to guide the intervention development process (e.g. 6Squid (16) or The Person Based Approach to Intervention Development (17)). Where a formal intervention development approach is used, it is helpful to describe the process that was followed, including any deviations. More general approaches to intervention development also exist and have been categorised as follows (3):- Target Population-centred intervention development; evidence and theory-based intervention development; partnership intervention development; implementation-based intervention development; efficacy-based intervention development; step or phased-based intervention development; and intervention-specific intervention development (3). These approaches do not always have specific guidance that describe their use. Nevertheless, it is helpful to give a rich description of how any published approach was operationalised	Page 4-5 (Introduction) Page 6 (Study design)	
5. Report how evidence from different sources informed the intervention development process.	Intervention development is often based on published evidence and/or primary data that has been collected to inform the intervention development process. It is useful to describe and reference all forms of evidence and data that have informed the development of the intervention because evidence bases can change rapidly, and to explain the manner in which the evidence and/or data was used. Understanding what evidence was and was not available at the time of intervention development can help readers to assess transferability to their current situation.	Page 7-13 (Development of the intervention)	
6. Report how/if published theory informed the intervention development process.	Reporting whether and how theory informed the intervention development process aids the reader's understanding of the theoretical rationale that underpins the intervention. Though not mentioned in the e-Delphi or consensus meeting, it became increasingly apparent through the development of our guidance that this theory item could relate to either existing published theory or programme theory	Page 4-5 (Introduction) Page 6 (Study design) Page 7 (Theory)	
7. Report any use of components from an existing intervention in the current intervention development process.	Some interventions are developed with components that have been adopted from existing interventions. Clearly identifying components that have been adopted or adapted and acknowledging their original source helps the reader to understand and distinguish between the novel and adopted components of the new intervention.	The intervention is based on existing evidence-based knowledge in Senior Alert. See figure 5.	
8. Report any guiding principles, people or factors that were prioritised when making decisions during the intervention development process.	Reporting any guiding principles that governed the development of the application helps the reader to understand the authors' reasoning behind the decisions that were made. These could include the examples of particular populations who views are being considered when designing the intervention, the modality that is viewed as being most appropriate, design features considered important for the target population, or the potential for the intervention to be scaled up.	Page 7-13 (Development of the intervention)	

Item description	Explanation	Page in manuscript where item is located	Other*
9. Report how stakeholders contributed to the intervention development process.	Potential stakeholders can include patient and community representatives, local and national policy makers, health care providers and those paying for or commissioning health care. Each of these groups may influence the intervention development process in different ways. Specifying how differing groups of stakeholders contributed to the intervention development process helps the reader to understand how stakeholders were involved and the degree of influence they had on the overall process. Further detail on how to integrate stakeholder contributions within intervention reporting are available (19).	Page 7-13	(Development of the intervention)
10. Report how the intervention changed in content and format from the start of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	Page 12 (Analysed the data from the focus group interviews and workshops) + Page 12-13 (Third phase)	
11. Report any changes to interventions required or likely to be required for subgroups.	Specifying any changes that the intervention development team perceive are required for the intervention to be delivered or tailored to specific sub groups enables readers to understand the applicability of the intervention to their target population or context. These changes could include changes to personnel delivering the intervention, to the content of the intervention, or to the mode of delivery of the intervention.	Page 12 (Analysed the data from the focus group interviews and workshops) + Page 12-13 (Third phase) + Page 13-16 (Results)	
12. Report important uncertainties at the end of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	Page 16-18 (Discussion)	
13. Follow TIDieR guidance when describing the developed intervention.	Interventions have been poorly reported for a number of years. In response to this, internationally recognized guidance has been published to support the high quality reporting of health care? interventions ⁵ and public health interventions ¹⁴ . This guidance should therefore be followed when describing a developed intervention.	The description of the intervention follows TIDieR	
14. Report the intervention development process in an open access format.	Unless reports of intervention development are available people considering using an intervention cannot understand the process that was undertaken and make a judgement about its appropriateness to their context. It also limits cumulative learning about intervention development methodology and observed consequences at later evaluation, translation and implementation stages. Reporting intervention development in an open access (Gold or Green) publishing format increases the accessibility and visibility of intervention development research and makes it more likely to be read and used. Potential platforms for open access publication of intervention development include open access journal publications, freely accessible funder reports or a study web-page that details the intervention development process.	Submitted to the BMJ Open	

*e.g. if item is reported elsewhere, then the location of this information can be stated here.

BMJ Open

The STAIR OF KNOWLEDGE – a codesigned intervention to prevent pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes in Sweden: development of a complex intervention

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Title

The STAIR OF KNOWLEDGE – a codesigned intervention to prevent pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes in Sweden: development of a complex intervention

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Abstract

Objectives: To describe the development of a codesigned complex intervention intended to prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes.

Design: A complex intervention development study. The development of the intervention was conducted in three phases. We established contact with stakeholders in the municipality, updated us of current status of the literature in this area and conducted studies in the local context (1). We codesigned the intervention in workshops together with end users (2). We codesigned the final outline of the intervention in an iterative process with stakeholders (3).

Setting: Nursing homes in the municipality in southern Sweden.

Participants: End users (n=16) in nursing homes (n=4) codesigned the intervention together with the research group in workshops (n=4) in March-April 2022. Additionally, stakeholders (n=17) who were considered to play an important role in developing the intervention participated throughout this process. Data were analysed using reflexive thematic analysis.

Results: Four workshops were conducted with end users (n=16) and thirteen meetings with stakeholders (n=12) were held during the development process. The intervention aims to bridge the evidence-practice gap regarding the preventive care process of the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes. The intervention is aimed at end users, lasts for three weeks and is divided into two parts. First, end users obtain knowledge on their own by following written instructions. Second, they meet, interact and discuss the knowledge acquired during part one.

Conclusion: The intervention is robustly developed and thoroughly described. The study highlights the extensive process that is necessary for developing tailored complex interventions. The description of the entire development process may enhance the replicability of this intervention. The intervention needs to be tested and evaluated in an upcoming feasibility study.

Trial number: Clinical Trial NCT05308862.

Strengths

- Inspired by the Medical Research Council guidelines for complex intervention, a robust development process was undertaken based on the literature and research conducted in the local context prior to developing the complex intervention.
- A complex intervention was codesigned both with and for nurse aides, registered nurses and managers in workshops. Additionally, key persons working in the municipality were engaged in the development of this tailored intervention.
- To bridge the evidence-practice gap regarding the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes, knowledge translation strategies were applied during the development process in accordance with the action part of the knowledge-to-action framework.
- A thorough description of the entire development process may enhance the replicability of the current intervention.

Limitations

- One limitation of the development process was that this design is time- and resource-consuming. On the other hand, this was necessary to develop a tailored complex intervention that might enhance the likelihood of successful implementation. The transferability of the tailored intervention to other nursing homes might also be a limitation.

Introduction

There remains an evidence-practice gap in preventing the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes^{1 2}. These health risks cause a major burden for older persons³ and they are costly for the health care system⁴. Since older persons are more vulnerable to these health risks⁵ and considering the increasing ageing population globally, particularly with regard to older persons aged 80 years or older⁶, evidence-based preventive work is crucial to manage this demographic challenge and, importantly, these health risks among older persons.

In Sweden, there is a national quality register, Senior Alert, providing an individualized, standardized, structured and systematic preventive care work process for older persons 65 years or older who are at risk of pressure ulcers, malnutrition, poor oral health and falls⁷. Senior Alert provides evidence-based knowledge aimed at preventing these health risks to enable a healthy ageing among older persons⁸; in addition, it can increase cost efficiency⁹. However, a lack of knowledge among those working with older persons has been identified as one major challenge regarding to preventive work^{2 10}. As a result, these health risks continue to be prevalent⁷. For instance, approximately every third older person living in a nursing home faces at least one of these health risks, and every tenth older person faces all four of these health risks¹. Additionally, not all older persons who are at risk have planned care interventions^{11 12} and there is a mismatch between identified risks and planned and performed care interventions^{13 14}, thus indicating an evidence-practice gap and consequently, highlighting the urgent need of translating knowledge into practice.

Nevertheless, this is not unique to Sweden or this context; in contrast, health systems worldwide face the shared challenge of translating knowledge into practice¹⁵. Knowledge translation has been defined as “*a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve health care of people in the country, provide more effective health service and products and strengthen the health care system*”, p. 165¹⁶. Ineffective knowledge translation can result in an evidence-practice gap¹⁷ and, worryingly, lead to situations in which patients are denied interventions that have been proven to be beneficial¹⁸, which in turn can result in a reduction in their quality of life¹⁹.

To bridge this evidence-practice gap, conceptual frameworks are recommended²⁰. The knowledge-to-action (KTA) framework is intended to help the parties involved in the process of knowledge translation¹⁸. The KTA framework is also appropriate when addressing an evidence-practice gap¹⁵ and conducting pragmatic research¹⁸.

As a part of translating knowledge into practice and promoting knowledge use by end users²¹, the engagement of both researchers and stakeholders in research is crucial²². Engaging stakeholders at an early stage in the development of solutions that can be applied to real world settings is essential according to the Medical Research Council's (MRC) framework for complex interventions²³. Complex interventions have multiple components, target multiple groups or levels of an organization and attempt to affect multiple outcomes²³. Additionally, for complex interventions to be most useful to end users, the local context must be taken into account²⁴. Since it is well underpinned that organizational factors hinder preventive work in nursing homes^{2 25}, considering and understanding the local context and integrating it into the process of intervention development is crucial²⁶.

Consequently, change in the practices of nursing homes is considered to be complex²⁷, but if complex interventions are tailored to the local context²⁸, including the targets of the intervention^{23 24} and is directly relevant to them²⁹, such interventions could be successful.

Aim

The aim of this study was to describe the development of a codesigned complex intervention intended to prevent pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes.

Methods

Definitions

Nursing homes were defined based on the definition provided by Neziraj et al. (2021)¹: residential care homes where older persons live and receive municipal health care.

Health care personnel and managers were defined based on the definition provided by Neziraj et al. (2021) as follows²:

Nurse aide: a person with a secondary degree in nursing, involves three years of study in high school *or* a person without any formal education in nursing.

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3 *Registered nurse*: a person with a bachelor's degree in nursing, which involves three years of
4 study at university.
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7 *Manager*: a person who is in charge of nurse aides or registered nurses.
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10 *End users*: nurse aides, registered nurses and managers working in nursing homes.
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12 *Stakeholders*: key persons working in the municipality who are considered to play an
13 important role in the development and implementation of the intervention.
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16 **Study context and setting**

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18 In nursing homes, nurse aides are the main providers of care and services and are on duty
19 around the clock. Nurse aides work under the regulations of the Social and Services Act
20 (SFS)³⁰ but are also delegated tasks according to the Health and Medical Services Act
21 (HSL)³¹, usually by registered nurses. Registered nurses guide care in nursing homes and
22 work under the regulations of HSL³¹. In the current setting, a large town located in southern
23 Sweden with 39 nursing homes, one registered nurse (or occasionally more depending on the
24 size of the nursing home) is located in the nursing home during office hours but is also
25 available at any other time. Managers who are in charge of the care and services provided by
26 the nurse aides are located at their respective nursing homes during office hours.
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30 For transparency, the research group (n=5) positions are reported; four of the researchers hold
31 positions as either doctoral students (MN), associated professors (MAX), professors (CK) or
32 senior lectures (PH) at the affiliated university. The last author (MA) is a PhD and hold the
33 position as a research and development coordinator in the municipality where the study was
34 conducted. All the authors are registered nurses, and two of them (MN, MA) specialize in
35 elderly care and have worked in this context previously,
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39 In addition, a reference group was created, which consisted of experts (n=7) drawn from the
40 local context; nurse aide (n=1), managers in charge of nursing homes (n=2), head of managers
41 in charge of registered nurses (n=1), development managers (n=2) and head of the nursing
42 homes in the municipality (n=1).
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45 **Study design**

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47 The current study describes the development of a codesigned complex intervention and is a
48 part of the PROSENIOR program (<https://mau.se/en/research/projects/prosenior/>). This part
49 of the PROSENIOR program aims to develop, test and evaluate a codesigned complex
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3 intervention to prevent pressure ulcers, malnutrition, poor oral health and falls among older
4 persons living in nursing homes in a two-arm pragmatic cluster randomized trial. The main
5 purpose of the randomization was to assess the feasibility of the procedure and will be
6 reported in an upcoming study. The control arm was therefore not included in the current
7 study. In the current study, the randomization aimed to invite end users allocated to the
8 intervention arm to develop a codesigned complex intervention.
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14 The development of the codesigned complex intervention (hereafter called the intervention)
15 was conducted in three phases. The phases are described below. The development of the
16 current intervention was conducted in a pragmatic paradigm as it is intended to work in a real-
17 world setting²⁹; this process was inspired by the MRC guidelines for complex interventions²⁴,
18 applied the KTA framework¹⁸ and engaged end users and stakeholders in the process of
19 codesign³².
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25 We follow the guidance for reporting intervention development studies (GUIDED)³³ when
26 describing the development of the intervention and the template for intervention description
27 and replication (TIDieR) checklist and guide³⁴ when describing the intervention. We use
28 “development” to refer to the whole process of intervention development and “design” to
29 indicate the intervention content, format and delivery.
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34 **Patient and public involvement**

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36 Patients or informal caregivers were not involved in the research process. End users
37 codesigned the intervention with the research group in workshops. Stakeholders were also
38 involved in this research; they supported the research group throughout the entire
39 development of the intervention by contributing their valuable knowledge. All engagement is
40 described in detail in the section “Development of the intervention” below.
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46 **Development of the intervention**

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48 We developed the intervention in three phases and applied the KTA framework in all phases
49 (Figure 1).
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52 *Theory*

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54 The KTA framework takes implementation strategies into account already in the development
55 phase¹⁸, which promotes and sustains practice change¹⁵. We applied the KTA framework
56 because it offers a structured and systematic approach to translate knowledge into practice¹⁸.
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3 It comprises two parts: knowledge creation and the action cycle. Since evidence-based
4 knowledge is already available to end users in the quality register Senior Alert, the action
5 cycle was applied during the development of the current intervention. The action cycle
6 consists of the following steps: 1. *Identify the problem, identify and review selected*
7 *knowledge, 2. Adapt knowledge to the local context, 3. Assess barriers to knowledge use, 4.*
8 *Select and tailor implementation strategies, 5. Monitor knowledge use, 6. Evaluate the*
9 *outcomes and 7. Sustain knowledge use*^{18 35}. Steps 1-4 the action cycle were applied
10 throughout the development process of developing the intervention in an iterative, dynamic
11 and permeable way.
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19 ***Phase one***

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21 During this phase, we established contact with stakeholders in the municipality, updated us of
22 the current status of the literature in this area and conducted studies in the local context.
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25 *Establishing contact with stakeholders in the municipality*

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27 Initially, we established contact and met with the head of the nursing homes in the
28 municipality. The reference group was created in this phase (described in the paragraph
29 “Study context and setting” above).
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33 *Searching for literature and conducting studies in the local context*

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35 As a part of step 1 in the KTA framework, *identify the problem, identify and review selected*
36 *knowledge*, firstly, we updated us of the current status of the literature regarding prevention of
37 pressure ulcers, malnutrition, poor oral health and falls and intervention studies in this area.
38 Subsequently, we conducted a cross-sectional study to determine the prevalence of the risks
39 of pressure ulcers, malnutrition, poor oral health and falls in nursing homes in southern
40 Sweden¹.
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47 As a part of steps 2-3 in the KTA framework, *adapt knowledge to the local context and assess*
48 *barriers to knowledge use*, we conducted focus group interviews (n=5) with end users (n=21)
49 who worked in nursing homes to prevent pressure ulcers, malnutrition, poor oral health and
50 falls². The focus group interviews lasted between 63 and 106 min (mean 83 min). A detailed
51 description of this study and its participants is provided in Neziraj et al². Additionally, we
52 asked the end users included in our previous study² how an optimal intervention could be
53 designed to prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among
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3 older persons in nursing homes. These particular data were targeted for the current study.
4 Hence, these data were not reported in our previous study, but are included, analysed and
5 reported in our current study.
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8 *Phase two*

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10 During this phase, we recruited and randomized nursing homes. Subsequently, we invited end
11 users in the intervention arm to participate in workshops, and planned and conducted the
12 workshops. We also analysed the specific data regarding intervention design drawn from the
13 focus group interviews (see the previous paragraph on phase one for clarification) and the
14 workshops.
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20 *Recruiting and randomizing nursing homes*

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22 Since the current study is a part of a two-arm pragmatic cluster randomized trial,
23 randomization was primarily conducted at this stage to assess the feasibility of the procedure
24 in an upcoming study. In the current study, however, randomization aimed to recruit end users
25 in nursing homes allocated to the intervention arm to codesign an intervention together with
26 the research group in workshops (Figure 2). The nursing home is the cluster and the unit of
27 allocation. Due to the nature of the design, the cluster randomization of nursing homes was
28 unblinded.
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35 Inclusion criteria for the study were nursing homes working with and registered in the quality
36 register Senior Alert. We recruited eligible nursing homes (n=21) to participate in the study
37 via digital meetings. In total, eight nursing homes agreed to participate and were cluster
38 randomized using a computerized program to either the intervention (n=4) or control arm
39 (n=4). Subsequently, we invited end users (n=118) working in nursing homes in the
40 intervention arm to participate in workshops intended to develop a tailored intervention
41 together with the research group; the invitations were extended both via a digital information
42 video and in written form. The remaining end users (n=184) working in the nursing homes
43 who were allocated to the control arm continued with their usual care routine.
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51 *Conducting workshops*

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53 As a part of steps 2-4 in the KTA framework, *adapt knowledge to the local context, assess*
54 *barriers to knowledge use* and *select and tailor implementation strategies*, we conducted
55 workshops with end users. In total, four workshops were conducted, which featured two nurse
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3 aides, one registered nurse and one manager in each workshop; the workshops were
4 conducted over the course of four weeks (March-April 2022). The workshops were kept small
5 to offer the end users the possibility of exhibiting activity and creativity³⁶. The first author
6 (MN) led the workshops together with one of the coauthors (all coauthors participated in one
7 workshop each). The workshops were intended to serve as a place in which participants could
8 learn together and discuss the design of the intervention in four different stations (Table 1).
9 The end users engaged in active discussion and wrote creative ideas and suggestions on the
10 walls and the board in a lecture hall designed for the purpose of encouraging creative
11 pedagogy. In the first station, the end users were asked to discuss the risks of pressure ulcers,
12 malnutrition, poor oral health and falls and the care interventions that should be applied. In
13 the second station, they were asked to discuss and identify barriers and facilitators they had
14 encountered in their own work regarding the preventive care process stipulated by Senior
15 Alert (identify a risk, assess causes and plan, undertake and evaluate care intervention).
16 Barriers were written down on pink post-it notes, while facilitators were written down on
17 green post-it notes. These post-it notes were subsequently placed at the appropriate location
18 on the board with regard to the predawn preventive care process. The focus of the discussions
19 at station three was on the end users' needs and the support they needed throughout the
20 preventive care process. In the fourth station, they were asked to discuss the core components
21 of the intervention, how to provide follow-ups and implementation strategies. After
22 completing each workshop, MN photographed and briefly summarized the written data from
23 each station. This summary was used if the end users in the subsequent workshop reached an
24 impasse and/or discussed and wrote similar suggestions and ideas to those proposed by the
25 end users in the previous workshop. Each workshop lasted for three hours, and the discussions
26 were audio recorded to support the written data collection during the analysis.
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Table 1. Workshop content (n=4).

Workshop	Station	Content	Examples of questions to discuss
Workshop 1-4	Station 1	Case regarding an older person at risk of pressure ulcers, malnutrition, poor oral health and falls living in a nursing home	<ul style="list-style-type: none"> • What would you have done in this case regarding these four risks? • Are there any good examples? What can you learn from good examples? • What additional knowledge do you need regarding these four risks in order to produce a risk assessment and provide adequate care interventions?
	Station 2	Senior Alert's care process	<ul style="list-style-type: none"> • Place green/pink post-it notes on the care process regarding what works/what can be improved in your own work and workplace.
	Station 3	End users needs' and the support they need regarding preventive work	<ul style="list-style-type: none"> • What do you need in your preventive work? • Why is this important, and what is most important (rank 1-3)? • Who needs help in the context of preventive work? • Who should be involved and in what way? • What is necessary for it to be feasible? • How can you work better/smarter? • How can you work in a more sustainable way?
	Station 4	Core components of the intervention	<ul style="list-style-type: none"> • What should be included in the intervention? • Who should it target? • How should it be designed? • How much/often/for how long should the intervention take place? • How should it be followed up? • Where should it be implemented? • How should it be implemented?

Analysing the data from the focus group interviews and the workshops

The analysis was guided by the six phases of reflexive thematic analysis described by Braun and Clarke^{37 38}: 1. *Familiarizing with the data*, 2. *Coding*, 3. *Generating initial themes*, 4. *Reviewing the identified themes*, 5. *Defining and naming the themes* and 6. *Producing the report*. Thematic analysis was chosen because it facilitates a flexible analysis process but simultaneously provides researchers with the core skills they need to conduct the analysis.

To familiarize ourselves with the data, MN and MA read the transcripts from the focus group interviews, including the data specifically collected for the current study, and the written data collected from the workshops. In addition, MN listened to all the audio-recorded discussions from the workshops meticulously. During the process of reading the data, MN and MA reflected on and generated initial codes. Subsequently, MN and MA met and discussed these initial codes (1). Thereafter, MN and MA separately engaged in a process of identifying and coding entities of interest in relation to the design of the intervention, giving equal attention to all the data (2). The initial codes were then sorted into their core components in relation to the design of the intervention (3). Next, the core components were reviewed by MN to determine whether any relevant data regarding the design of the intervention had been missed (4). Subsequently, MN designed an outline of the intervention. This outline contained the intervention's proposed design, including its content, format, plan for delivery and duration. In the following step of the analysis, the entire research group met and discussed the design of the outline of the intervention. During this step, MN continuously revised the outline of the intervention following discussions within the research group (5). Then, the outline of the intervention was redesigned by MN. The redesigned outline of the intervention was then presented to the research group before it was presented to the stakeholders. The process of producing the final design of the intervention is described in phase three below (6).

Phase three

As part of steps 2-4 in the KTA framework, *adapt knowledge to the local context, assess barriers to knowledge use and select and tailor implementation strategies*, MN and MA met regularly with stakeholders in structured meetings to present and discuss the outline of the intervention. MN documented all the meetings. MA works within the municipality and thus facilitated contact with stakeholders who were considered to play an important role in this part of designing the intervention. Since this part of the process was dynamic and iterative and because all relevant uncertainties had not been addressed in the redesigned outline of the

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3 intervention, it was helpful to meet stakeholders for the purpose of identifying and addressing
4 the remaining uncertainties regarding the content, format, delivery and duration of the
5 intervention. This part of the process was time-consuming and required a back-and-forth
6 process involving meetings and discussions between MN and MA, within the entire research
7 group and with the stakeholders. Next, the redesigned outline of the intervention was adjusted
8 by MN in accordance with the results of these meetings and discussions (Figure 3). Finally,
9 MN investigated whether any data from the focus group interviews and the workshops had
10 been missed, since these data were intended to serve as the foundation for designing the final
11 outline of the intervention. The final design of the intervention, the STAIR OF
12 KNOWLEDGE (Figure 4), is described below.

21 Results

22 Findings from our previous studies^{1 2} in phase one showed that the prevalence of the risk for
23 pressure ulcer, malnutrition, poor oral health and falls is still high in the local context.

24 Furthermore, findings from phase one suggested that individuals working with older persons
25 in nursing homes need increased knowledge concerning how to prevent these health risks.

26 Since existing evidence and knowledge concerning how to prevent these health risks is
27 already contained in Senior Alert, the challenge seems to lie in the evidence-practice gap.

28 Consequently, in phase two and three, a tailored intervention was codesigned with end users,
29 stakeholders and the research group to reduce the evidence-practice gap. The final design of
30 the intervention is presented below.

31 A majority of the end users (n=16) in workshops (n=4) were women (n=13), between the ages
32 of 28-63 years (mean 53), and had worked for 3-41 years (mean 18). The meetings (n=13)
33 with stakeholders (n=12) lasted between 60-180 min (mean 134 min).

34 The final design of the intervention

35 The final design of the intervention was described in line with the TIDieR checklist³⁴
36 (Supplementary file).

37 The STAIR OF KNOWLEDGE consists of *the foundation and stairs 1-6*, lasts for three
38 weeks and is divided into two parts. Part one, including *the foundation and stairs 1-5*, takes
39 place throughout the entire intervention period (weeks 1-3) and is delivered digitally to end
40 users in the nursing homes via their workplace email addresses. Part two includes *stair 6* and
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3 takes place during the last week of the intervention period (week 3) in the nursing homes in
4 question (Figure 4).
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6 7 **The content of the intervention** 8

9 *Part one of the intervention: the foundation and stairs 1-5*

11 End users emphasized uncertainties of different professionals' responsibilities regarding the
12 preventive work. For instance, they highlighted that it is highly relevant for respective
13 professional to know "who does what" regarding the preventive working. Hence, *the*
14 *foundation* is intended to facilitate for different professionals regarding responsibilities for
15 respective profession and working routine in the local context. *The foundation* provide end
16 users with knowledge and awareness of how to work preventively in the context of an existing
17 local working routine and is intended to represent "the ground to stand on".
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20 Furthermore, end users expressed a need of increased knowledge regarding the health risks
21 and the entire preventive working process. They stressed the importance of basic knowledge
22 when working with older persons in nursing homes. According to end users, not all of them
23 has basic knowledge in how to prevent these health risks among older persons. This was
24 particularly common among temporary workers. To meet their need, *stairs 1-4* provide the
25 end users with general knowledge about risks of pressure ulcers, malnutrition, poor oral health
26 and falls according to the care process suggested by the quality register Senior Alert (*stair 1*),
27 risk assessment instruments (*stair 2*), the underlying causes of these risks (*stair 3*) and
28 preventive care interventions (*stair 4*). *Stairs 1-5* provide end users with website links that
29 allow them to both read texts and watch videos. *Stairs 1-4* are mandatory for all professionals.
30 *Stair 5* provides end users with knowledge of how to register in the quality register Senior
31 Alert and is mandatory only for users who have access to and the responsibility to register in
32 the quality register Senior Alert.
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47 *Part two of the intervention: stair 6*

49 Although it was necessary for end users to increase their knowledge on their own regarding
50 the preventive work, they particularly highlighted the importance of physical meetings. This
51 was also stressed as important by stakeholders and was considered as a complement to the
52 first part of the intervention. Therefore, in part two, *stair 6*, a facilitator (MN) meets with end
53 users to interact with them and discuss the knowledge acquired during part one. The meetings
54 will be structured including discussions based on different cases related to pressure ulcers,
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3 malnutrition, poor oral health and falls. End users will also perform risk assessments, identify
4 the underlying causes and plan accurate care interventions based on these cases. Additionally,
5 end users will identify environmental risk factors related to the risks of pressure ulcers,
6 malnutrition, poor oral health and falls in their own workplace. They will also discuss and
7 generate ideas how to follow up on the preventive care process on an organizational level.
8 This part of the intervention is intended to inspire end users to prevent pressure ulcers,
9 malnutrition, poor oral health and falls among older persons in nursing homes.
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15 **The format of the intervention**

16 *Part one of the intervention: the foundation and stairs 1-5*

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18 From end users' perspective, it was important with a clear format. They expressed a need of a
19 structured, readable and colourful working "manual". Hence, the format of the intervention is
20 designed as colourful stair with the intention to visualize the entire preventive working
21 process. To enhance the structure, end users are provided with written instructions in
22 respective stair. Furthermore, stakeholder emphasized the need of a "self-check box" for end
23 users when completing the foundation and stairs in the intervention. Stakeholder believed that
24 this could increase participation and involvement among end users. Since both end users and
25 stakeholders stressed that there are many end users that do not have the Swedish language as
26 their native language, the language is adjusted to suit the local context. Furthermore, end users
27 expressed that the format of the intervention should consider different ways of learning. This
28 was also highlighted as important by stakeholders. Hence, the format consist of both reading
29 texts and watching videos. Moreover, end users and stakeholders emphasized that a digital
30 intervention could be a sustainable solution.
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43 *Part two of the intervention: stair 6*

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45 End users and stakeholder were in agreement that it is necessary to meet and discuss.
46 Therefore, in part two of the intervention, end users meet in their respective nursing home.
47 Also, the format of this part of the intervention was designed as an inspiration to raise
48 awareness of the preventive work among end users.
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53 **The delivery of the intervention**

54 *Part one of the intervention: the foundation and stairs 1-5*

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3 The intervention will be delivered via email to managers in nursing homes. Subsequently,
4 respective manager will forward the intervention via workplace email addresses to nurse aides
5 and registered nurses. The end users highlighted that some learn better individually while
6 others learn better in group. Therefore, they are permitted to choose if they want to read texts
7 and watch videos individually and/or in group. *The foundation and stairs 1-5* is anticipated to
8 take approximately 10 minutes, 60 minutes, 20 minutes, 10 minutes, 30 minutes and 60
9 minutes respectively for end users to complete. End users can choose to complete this part of
10 intervention at once or divide it during working hours.
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17 *Part two of the intervention: stair 6*

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20 Part two of the intervention will be delivered by a facilitator (MN) who will moderate
21 sessions lasting approximately 30 minutes each, Monday-Friday, in the nursing homes in
22 question. If end users participate in all the sessions during this week, the planned amount of
23 time is two and half hours for each end user.
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27 **Discussion**

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29 The current codesigned complex intervention, the STAIR OF KNOWLEDGE, was developed
30 together with end users in workshops in an active and creative way. Stakeholders were also
31 engaged in an iterative and dynamic way throughout the development of the intervention, as
32 an important part of undertaking implementation strategies already in the development
33 phase³⁹. As recommended by the MRC framework²⁴, we meticulously considered the
34 relationship between the intervention and its context when developing the intervention.
35 Furthermore, we followed the strategies for knowledge translation included in the KTA
36 framework¹⁸. Hence, the strengths exhibited by the development of this complex intervention
37 lie in the fact that it was developed both together with and for end users and engaged
38 stakeholders who are considered to play an important role in the development and
39 implementation process. The current intervention is intended to work in a real-world setting
40 and aims to bridge the evidence-practice gap regarding the process of preventing the risks of
41 pressure ulcers, malnutrition, poor oral health and falls; ultimately, this intervention may
42 reduce these risks among older persons in nursing homes.
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54 When developing new intervention, the value of the used design process cannot be
55 understated⁴⁰. In fact, engagement of end users in a creative environment have been linked to
56 more robust research and development efforts, which in turn may drive more successful
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3 interventions outcome⁴⁰. Hence, the benefits of codesign are potentially substantial⁴¹. For
4 instance, engaging end users and stakeholders as design partners to the research group could
5 ensure that the intervention exhibits a better fit to their needs³². Engaging end users and
6 stakeholders early enables their experiences and requirements to be taken into account at the
7 start rather than a situation in which the researchers presume to know what is required³⁹. In
8 the current development process, although end users' and stakeholders' engagement ranged in
9 intensity from relatively passive to highly active, their engagement pervaded the entire
10 development process, and important decisions regarding the intervention design were made
11 by considering their input. Furthermore, because we engaged end users and stakeholders, the
12 current intervention was based on their own experiences regarding the evidence and
13 knowledge that are necessary throughout the entire process of preventing the risks of pressure
14 ulcers, malnutrition, poor oral health and falls. Engaging end users and stakeholders during
15 the developing process⁴² was also important in light of the local context since this enabled us
16 to identify facilitators and barriers in the environment in which the intervention will
17 eventually be implemented²⁶.
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30 A recent scoping review investigating education interventions for health professionals on fall
31 prevention in health care settings⁴³, highlighted that health professional education to prevent
32 fall is important. Nevertheless, the scoping review concluded that there are no uniform
33 education design principles utilized to date⁴³. Another review found that it was uncertain
34 whether education delivered in different format such as didactic or video-based format makes
35 a difference to health professionals' knowledge of pressure ulcers prevention. However,
36 education format in the current developed intervention was designed to fit end users' needs
37 and suit the local context, which may have benefits for the outcome.
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44 Considering and understanding the local context is also crucial when addressing an evidence-
45 practice gap²⁴. In this case, knowledge concerning the process of preventing the risks of
46 pressure ulcers, malnutrition, poor oral health and falls is already contained in the quality
47 register Senior Alert, but this evidence has not been fully translated into practice. Thus, we
48 focused on translating the existing knowledge contained in Senior Alert into practice.
49 However, if this knowledge is to be implemented effectively⁴⁴, it is crucial to employ a
50 conceptual framework²⁰. Therefore, we chose the KTA framework because it provided us
51 with knowledge translation strategies to reduce the evidence-practice gap¹⁸, and it was
52 suitable since the quality register Senior Alert is already in use. Furthermore, adapting
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3 knowledge to the local context and assessing barriers to knowledge use may enable the
4 research to have a greater impact⁴⁵, which could in turn reduce the evidence-practice gap.
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7 Successful intervention development is characterized as rigorous and scientific and leads to an
8 intervention that can be implemented in a real-world setting³³. The robust research process
9 used to develop the STAIR OF KNOWLEDGE intervention incorporates existing evidence,
10 the views of end users and stakeholders⁴¹, the local context and knowledge translation
11 strategies. Consequently, the use of knowledge translation strategies and the engagement of
12 end users who are embedded in the local context in the development of a tailored complex
13 intervention both for and with them could contribute to increased knowledge and awareness
14 of the entire process of preventive care. This may, in turn, reduce the evidence-practice gap
15 among end users and, importantly, reduce the risk of pressure ulcers, malnutrition, poor oral
16 health and falls among older persons in nursing homes. Furthermore, the engagement of
17 stakeholders already in the development process is likely to facilitate the implementation of
18 the current intervention.
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28 **Limitations**

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30 Although the development of this complex intervention has been completed, it is important to
31 acknowledge the limitations of the development process. First, only four clusters were
32 included in the development process. Nevertheless, since this part of the trial focused on the
33 development of an intervention rather than its evaluation and because the clusters were
34 recruited pragmatically, the clusters included in the trial could be considered sufficient.
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36 Second, although all end users in the intervention arm (n=118) were invited to participate in
37 workshops, only 16 participated. However, different professionals participated in the
38 workshops, and the discussions were energetic, active and creative. Third, although this
39 design is creative and can generate new ideas, it is time- and resource-consuming for all parties
40 involved. It requires end users and stakeholders to set aside time and expend extra effort in
41 their daily work. For researchers, this process requires careful planning to enable them to
42 coordinate, meet with many different persons repeatedly and be responsive to all parties
43 involved. However, although this design required the expenditure of time and resources, the
44 engagement of end users, stakeholders and researchers is meaningful and necessary to
45 develop successful interventions; ultimately, this design might have an impact on to prevent
46 the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in
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3 nursing homes. Furthermore, the current intervention might offer value when used by others
4 and could likely be adjusted to and tested in similar contexts.
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7 **Conclusion**

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9 The current codesign complex intervention, the STAIR OF KNOWLEDGE, which aims to
10 prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among older
11 persons in nursing homes, is robustly developed and thoroughly described. A careful
12 description of the entire development process and the intervention itself can enhance the
13 replicability of the current intervention. This article highlights the extensive process that is
14 necessary for the development of tailored complex interventions. Finally, this codesigned
15 complex intervention might result in more evidence-based practice concerning the entire
16 process of preventing the risks of pressure ulcers, malnutrition, poor oral health and falls and,
17 importantly, reduce these health risks among older persons in nursing homes. However,
18 uncertainties regarding the intervention itself remain. Thus, the STAIR OF KNOWLEDGE
19 must be tested and evaluated in an upcoming feasibility study before we continue to the stage
20 of conducting a full trial evaluation.
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30 **Ethical considerations**

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32 This trial was approved by the Swedish Ethical Review Authority (DNR 2019-06414). In
33 addition, written approval was requested and granted by the head of the department of elderly
34 care homes in the municipality in which this trial was conducted. All end users working in
35 eligible nursing homes were invited to participate in the workshops. Moreover, end users had
36 the right to withdraw from participation at any stage without providing reasons and bearing
37 any consequences. Participation in the workshops was based on written consent. The results
38 of this trial may be considered to contribute to scientific value on good ethical grounds, and
39 the benefits of participating in the trial outweigh the corresponding risks.
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48 **Funding statement**

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50 This research received financial support with regard to conducting the workshops from the
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52 research manuscript's design, conduct, analysis, interpretation or drafting.
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56 **CRediT authorship contribution statement**

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3 **Merita Neziraj:** Conceptualization, Methodology, Investigation, Writing – original draft,
4 Writing – review & editing, Validation, Formal analysis, Visualization. **Malin Axelsson:**
5 Conceptualization, Methodology, Investigation, Writing – review & editing, Validation,
6 Supervision. **Christine Kumlien:** Conceptualization, Methodology, Investigation, Writing –
7 review & editing, Validation, Supervision. **Peter Hellman:** Conceptualization, Methodology,
8 Investigation, Writing – review & editing, Validation, Supervision. **Magdalena Andersson:**
9 Conceptualization, Methodology, Investigation, Writing – review & editing, Validation,
10 Formal analysis, Supervision. All the authors read and approved the final version of the
11 manuscript.
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19 **Competing interests**

20
21 The authors have no conflicts of interest.

22 **Participant consent**

23
24 All participation in the workshops was based on written consent.

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26
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28 development of the intervention. We also thank the stakeholders who participated during this
29 process. Their enthusiastic participation was helpful in developing the STAIR OF
30 KNOWLEDGE intervention. The Derbring and Stölten foundation is acknowledged for its
31 financial support.
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33 **Data sharing statement**

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35 The data that support the development of the STAIR OF KNOWLEDGE intervention are not
36 publicly available to ensure confidentiality. All data relevant to the development are included
37 in the article. All figures and tables included in this article are original.
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38 Figure 1 - Phases one-three illustrate the process of developing the STAIR OF KNOWLEDGE
39 intervention, which took place between 2019 and 2022. Although the knowledge-to-action (KTA)
40 framework is viewed as a cycle by Graham and colleagues (2006), in this figure, the arrow illustrates
41 the fact that the KTA framework was applied throughout phases one-three of the development
42 process. The KTA framework was applied in an iterative and dynamic way in each phase and is
43 described in detail in the text.

44
45 Figure 2 - Flowchart of the two-arm pragmatic cluster randomized controlled trial. The dashed lines
46 illustrate an upcoming study. The current study focused on the development of the STAIR OF
47 KNOWLEDGE intervention.

48
49 Figure 3 - Note: T=how long the meeting lasted for, reported in minutes. MN=the first author.
50 MA=the last author.

51 The iterative and dynamic process of designing the final outline of the STAIR OF KNOWLEDGE
52 intervention between April and September 2022, including meetings and discussions with
53 stakeholders. In all the meetings, the first author participated. In addition, in some meetings also the
54 last author participated. The blue arrows illustrate that adjustments were made following each
55 meeting.
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58 Figure 4 - Final design of the STAIR OF KNOWLEDGE intervention.
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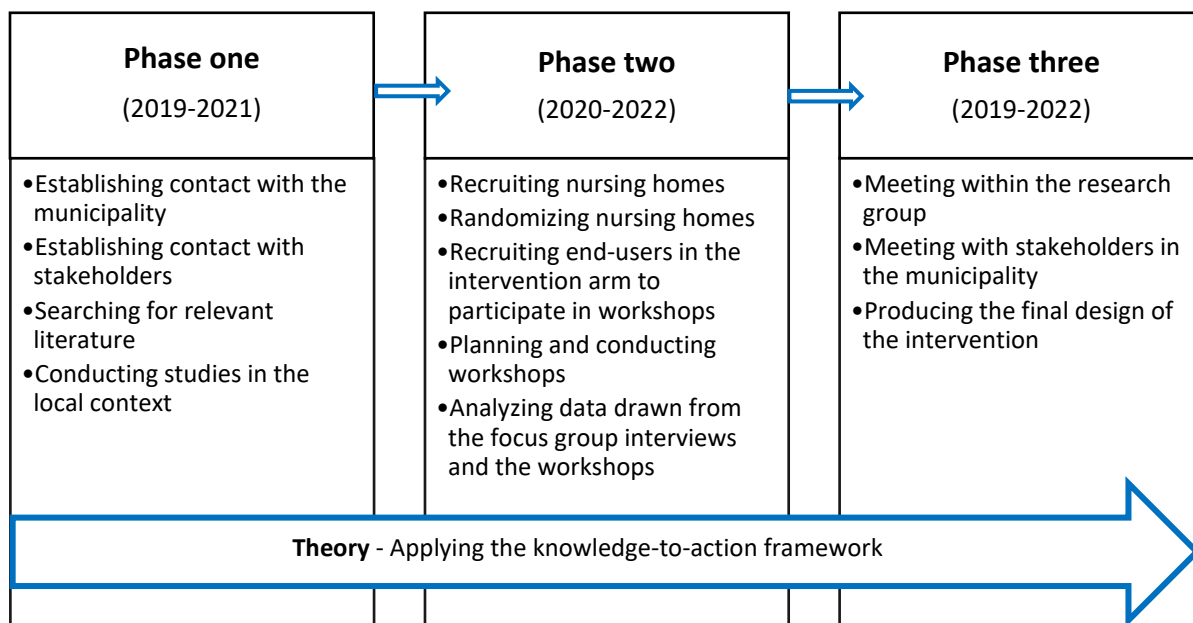


Figure 1. Phases one-three illustrate the process of developing the STAIR OF KNOWLEDGE intervention, which took place between 2019 and 2022. Although the knowledge-to-action (KTA) framework is viewed as a cycle by Graham and colleagues (2006), in this figure, the arrow illustrates the fact that the KTA framework was applied throughout phases one-three of the development process. The KTA framework was applied in an iterative and dynamic way in each phase and is described in detail in the text.

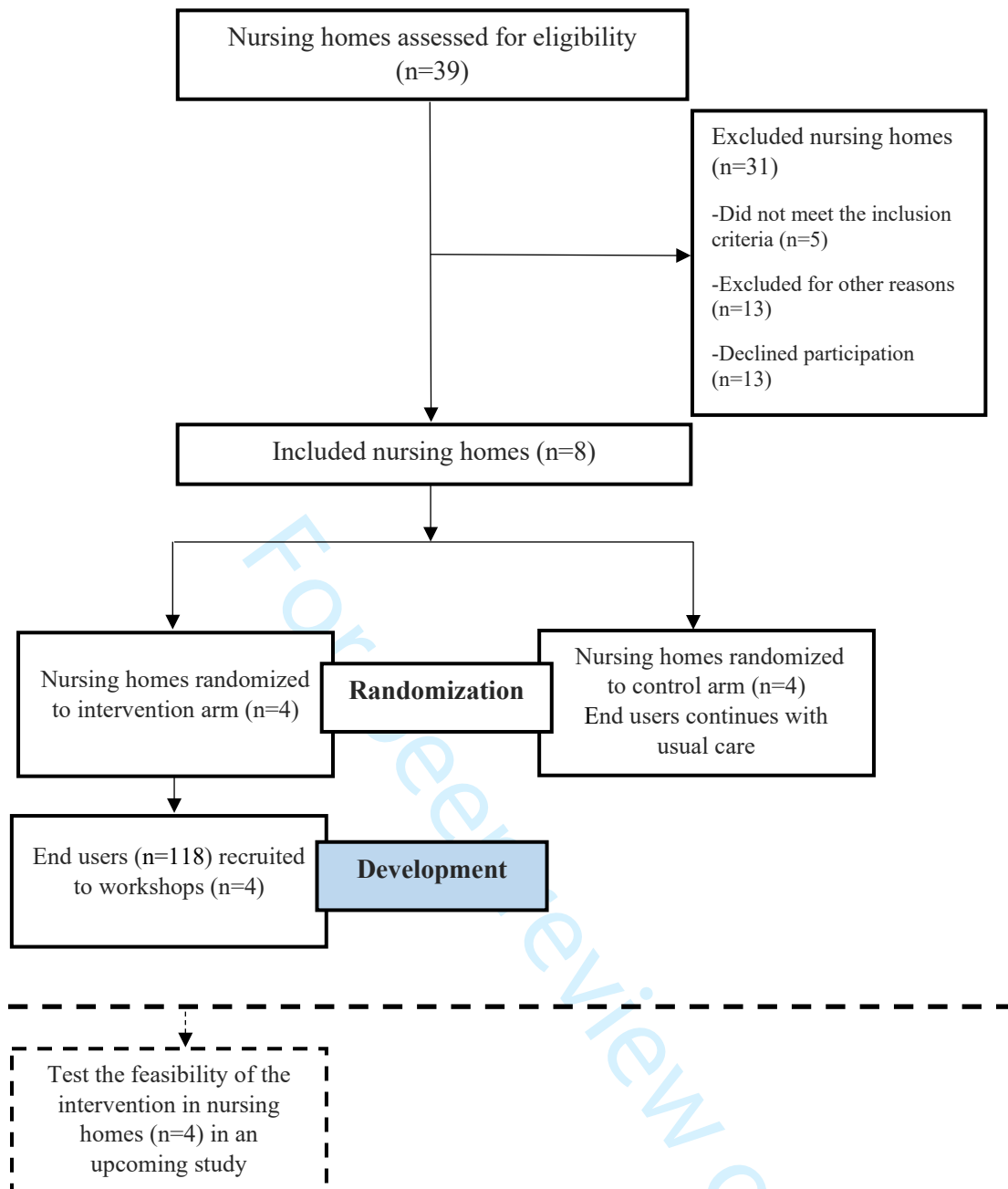


Figure 2. Flowchart of the two-arm pragmatic cluster randomized controlled trial. The dashed lines illustrate an upcoming study. The current study focused on the development of the STAIR OF KNOWLEDGE intervention.

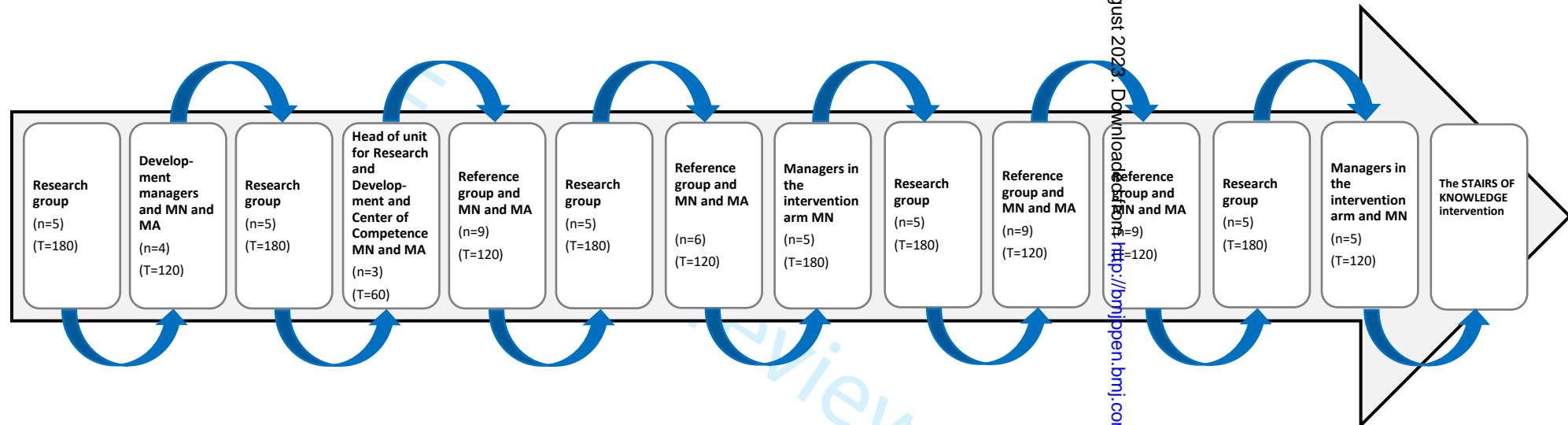
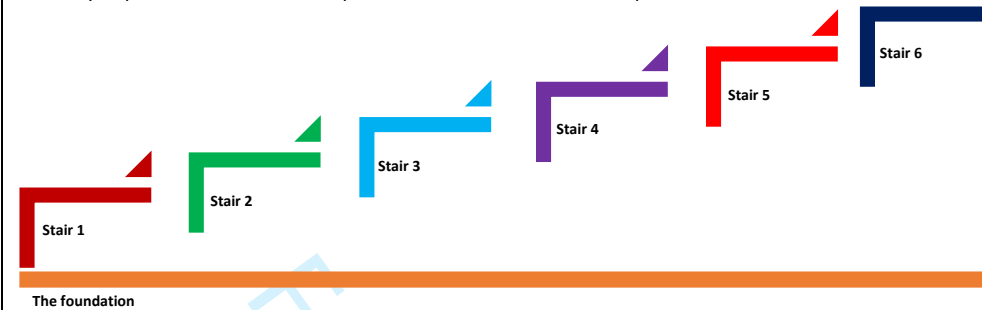


Figure 3. Note: T=how long the meeting lasted for, reported in minutes. MN=the first author. MA=the last author. The iterative and dynamic process of designing the final outline of the STAIR OF KNOWLEDGE intervention between April and September 2022, including meetings and discussions with stakeholders. In all the meetings, the first author participated. In addition, in some meetings also the last author participated. The blue arrows illustrate that adjustments were made following each meeting.

The STAIR OF KNOWLEDGE

The STAIR OF KNOWLEDGE is addressed to all nurse aides, registered nurses and managers who work with older persons in nursing homes. The STAIR OF KNOWLEDGE aims to increase knowledge regarding the preventive care necessary to prevent the risks of falls, pressure ulcers, malnutrition and poor oral health.



The foundation is mandatory for nurse aides, registered nurses and managers. **Stairs 1-4** and **stair 6** are mandatory for all nurse aides, registered nurses and managers. **Stair 5** is mandatory for individuals who register in Senior Alert. Follow the instructions below.

For your convenience, click the boxes as you progress through the STAIR OF KNOWLEDGE.

- | | | | |
|------------|--------------------------|------------|--------------------------|
| Foundation | <input type="checkbox"/> | Stair 4a-d | <input type="checkbox"/> |
| Stair 1a-d | <input type="checkbox"/> | Stair 5 | <input type="checkbox"/> |
| Stair 2a-d | <input type="checkbox"/> | Stair 6 | <input type="checkbox"/> |
| Stair 3 | <input type="checkbox"/> | | |

The foundation. Local working description of the entire preventive care working process.

- Link to the local working routine.

Stair 1a-d. General information regarding falls, pressure ulcers, malnutrition and poor oral health.

- Links to texts and videos regarding falls, pressure ulcers, malnutrition and poor oral health.

Stair 2a-d. Risk assessment of falls, pressure ulcers, malnutrition and poor oral health.

- Links to texts and videos regarding the risk assessment of falls, pressure ulcers, malnutrition and poor oral health.

Stair 3. Causes of falls, pressure ulcers, malnutrition and poor oral health.

- Link to text regarding the causes of falls, pressure ulcers, malnutrition and poor oral health.

Stair 4a-d. Preventive care interventions for falls, pressure ulcers, malnutrition and poor oral health.

- Links to texts regarding preventive care interventions for falls, pressure ulcers, malnutrition and poor oral health.

Stair 5. Registering in Senior Alert.

- Links to texts and videos regarding how to register in Senior Alert.

Stair 6. Inspiration week.

- Inspiration week focuses on preventive care intended to prevent the risks of falls, pressure ulcers, malnutrition and poor oral health in an inspiring and motivating way. The inspiration week will be organized by and for employees and managers. The inspiration week is preferably organized twice per year.

Figure 4. Final design of the STAIR OF KNOWLEDGE intervention.



Template for Intervention
Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
	The codesigned STAIR OF KNOWLEDGE intervention to prevent pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes: a complex intervention development study	Primary paper	Other † (details)
		Page or appendix number)	

<p>7. Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.</p>	<p>13-15 _____</p>	<p>_____</p>
<p>WHEN and HOW MUCH</p>		
<p>8. Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.</p>	<p>13-15 _____</p>	<p>_____</p>
<p>TAILORING</p>		
<p>9. If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.</p>	<p>15 _____</p>	<p>_____</p>
<p>MODIFICATIONS</p>		
<p>10.* If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).</p>	<p>N/A _____</p>	<p>_____</p>
<p>HOW WELL</p>		
<p>11. Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.</p>	<p>N/A _____</p>	<p>_____</p>
<p>12.* Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.</p>	<p>N/A _____</p>	<p>_____</p>

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement**. When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013**

1 **Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see
2 www.equator-network.org).
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For peer review only

GUIDED – a guideline for reporting for intervention development studies.

Supplementary File 1: Blank Checklist

Item description	Explanation	Page in manuscript where item is located	Other*
1. Report the context for which the intervention was developed.	Understanding the context in which an intervention was developed informs readers about the suitability and transferability of the intervention to the context in which they are considering evaluating, adapting or using the intervention. Context here can include place, organisational and wider socio-political factors that may influence the development and/or delivery of the intervention (15).	Page 6 (Study context and setting)	
2. Report the purpose of the intervention development process.	Clearly describing the purpose of the intervention specifies what it sets out to achieve. The purpose may be informed by research priorities, for example those identified in systematic reviews, evidence gaps set out in practice guidance such as The National Institute for Health and Care Excellence or specific prioritisation exercises such as those undertaken with patients and practitioners through the James Lind Alliance.	Page 4-5 (Introduction) Page 7-13 Development of the intervention)	
3. Report the target population for the intervention development process.	The target population is the population that will potentially benefit from the intervention – this may include patients, clinicians, and/or members of the public. If the target population is clearly described then readers will be able to understand the relevance of the intervention to their own research or practice. Health inequalities, gender and ethnicity are features of the target population that may be relevant to intervention development processes.	Page 7-13 (Development of the intervention) Page 13-16 (Results)	
4. Report how any published intervention development approach contributed to the development process	Many formal intervention development approaches exist and are used to guide the intervention development process (e.g. 6Squid (16) or The Person Based Approach to Intervention Development (17)). Where a formal intervention development approach is used, it is helpful to describe the process that was followed, including any deviations. More general approaches to intervention development also exist and have been categorised as follows (3):- Target Population-centred intervention development; evidence and theory-based intervention development; partnership intervention development; implementation-based intervention development; efficacy-based intervention development; step or phased-based intervention development; and intervention-specific intervention development (3). These approaches do not always have specific guidance that describe their use. Nevertheless, it is helpful to give a rich description of how any published approach was operationalised	Page 4-5 (Introduction) Page 6 (Study design)	
5. Report how evidence from different sources informed the intervention development process.	Intervention development is often based on published evidence and/or primary data that has been collected to inform the intervention development process. It is useful to describe and reference all forms of evidence and data that have informed the development of the intervention because evidence bases can change rapidly, and to explain the manner in which the evidence and/or data was used. Understanding what evidence was and was not available at the time of intervention development can help readers to assess transferability to their current situation.	Page 7-13 (Development of the intervention)	
6. Report how/if published theory informed the intervention development process.	Reporting whether and how theory informed the intervention development process aids the reader's understanding of the theoretical rationale that underpins the intervention. Though not mentioned in the e-Delphi or consensus meeting, it became increasingly apparent through the development of our guidance that this theory item could relate to either existing published theory or programme theory	Page 4-5 (Introduction) Page 6 (Study design) Page 7 (Theory)	
7. Report any use of components from an existing intervention in the current intervention development process.	Some interventions are developed with components that have been adopted from existing interventions. Clearly identifying components that have been adopted or adapted and acknowledging their original source helps the reader to understand and distinguish between the novel and adopted components of the new intervention.	The intervention is based on existing evidence-based knowledge in Senior Alert. See figure 5.	
8. Report any guiding principles, people or factors that were prioritised when making decisions during the intervention development process.	Reporting any guiding principles that governed the development of the application helps the reader to understand the authors' reasoning behind the decisions that were made. These could include the examples of particular populations who views are being considered when designing the intervention, the modality that is viewed as being most appropriate, design features considered important for the target population, or the potential for the intervention to be scaled up.	Page 7-13 (Development of the intervention)	

Item description	Explanation	Page in manuscript where item is located	Other*
9. Report how stakeholders contributed to the intervention development process.	Potential stakeholders can include patient and community representatives, local and national policy makers, health care providers and those paying for or commissioning health care. Each of these groups may influence the intervention development process in different ways. Specifying how differing groups of stakeholders contributed to the intervention development process helps the reader to understand how stakeholders were involved and the degree of influence they had on the overall process. Further detail on how to integrate stakeholder contributions within intervention reporting are available (19).	Page 7-13 (Development of the intervention)	
10. Report how the intervention changed in content and format from the start of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	Page 12 (Analysed the data from the focus group interviews and workshops) + Page 12-13 (Third phase)	
11. Report any changes to interventions required or likely to be required for subgroups.	Specifying any changes that the intervention development team perceive are required for the intervention to be delivered or tailored to specific sub groups enables readers to understand the applicability of the intervention to their target population or context. These changes could include changes to personnel delivering the intervention, to the content of the intervention, or to the mode of delivery of the intervention.	Page 12 (Analysed the data from the focus group interviews and workshops) + Page 12-13 (Third phase) + Page 13-16 (Results)	
12. Report important uncertainties at the end of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	Page 16-18 (Discussion)	
13. Follow TIDieR guidance when describing the developed intervention.	Interventions have been poorly reported for a number of years. In response to this, internationally recognized guidance has been published to support the high quality reporting of health care? interventions ⁵ and public health interventions ¹⁴ . This guidance should therefore be followed when describing a developed intervention.	The description of the intervention follows TIDieR	
14. Report the intervention development process in an open access format.	Unless reports of intervention development are available people considering using an intervention cannot understand the process that was undertaken and make a judgement about its appropriateness to their context. It also limits cumulative learning about intervention development methodology and observed consequences at later evaluation, translation and implementation stages. Reporting intervention development in an open access (Gold or Green) publishing format increases the accessibility and visibility of intervention development research and makes it more likely to be read and used. Potential platforms for open access publication of intervention development include open access journal publications, freely accessible funder reports or a study web-page that details the intervention development process.	Submitted to the BMJ Open	

*e.g. if item is reported elsewhere, then the location of this information can be stated here.

BMJ Open

The STAIR OF KNOWLEDGE – a codesigned intervention to prevent pressure ulcers, malnutrition, poor oral health and falls among older persons in nursing homes in Sweden: development of a complex intervention

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1
2
3 **1 Title**
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6 2 The STAIR OF KNOWLEDGE – a codesigned intervention to prevent pressure ulcers,
7 3 malnutrition, poor oral health and falls among older persons in nursing homes in Sweden:
8 4 development of a complex intervention
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1 **Abstract**

2 **Objectives:** To describe the development of a codesigned complex intervention intended to
3 prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among older
4 persons in nursing homes.

5 **Design:** A complex intervention development study. The development of the intervention was
6 conducted in three phases. We established contact with stakeholders in the municipality,
7 updated us of current status of the literature in this area and conducted studies in the local
8 context (1). We codesigned the intervention in workshops together with end users (2). We
9 codesigned the final outline of the intervention in an iterative process with stakeholders (3).

10 **Setting:** Nursing homes in the municipality in southern Sweden.

11 **Participants:** End users (n=16) in nursing homes (n=4) codesigned the intervention together
12 with the research group in workshops (n=4) in March-April 2022. Additionally, stakeholders
13 (n=17) who were considered to play an important role in developing the intervention
14 participated throughout this process. Data were analysed using reflexive thematic analysis.

15 **Results:** Four workshops were conducted with end users (n=16) and thirteen meetings with
16 stakeholders (n=12) were held during the development process. The intervention aims to
17 bridge the evidence-practice gap regarding the preventive care process of the risks of pressure
18 ulcers, malnutrition, poor oral health and falls among older persons in nursing homes. The
19 intervention is aimed at end users, lasts for three weeks and is divided into two parts. First,
20 end users obtain knowledge on their own by following written instructions. Second, they
21 meet, interact and discuss the knowledge acquired during part one.

22 **Conclusion:** The intervention is robustly developed and thoroughly described. The study
23 highlights the extensive process that is necessary for developing tailored complex
24 interventions. The description of the entire development process may enhance the replicability
25 of this intervention. The intervention needs to be tested and evaluated in an upcoming
26 feasibility study.

27 **Trial number:** Clinical Trial NCT05308862.

1 Strengths

- 2 • Inspired by the Medical Research Council guidelines for complex intervention, a
3 robust development process was undertaken based on the literature and research
4 conducted in the local context prior to developing the complex intervention.
- 5 • A complex intervention was codesigned both with and for nurse aides, registered
6 nurses and managers in workshops. Additionally, key persons working in the
7 municipality were engaged in the development of this tailored intervention.
- 8 • To bridge the evidence-practice gap regarding the risks of pressure ulcers,
9 malnutrition, poor oral health and falls among older persons in nursing homes,
10 knowledge translation strategies were applied during the development process in
11 accordance with the action part of the knowledge-to-action framework.
- 12 • A thorough description of the entire development process may enhance the
13 replicability of the current intervention.

14 Limitations

- 15 • One limitation of the development process was that this design is time- and resource-
16 consuming. On the other hand, this was necessary to develop a tailored complex
17 intervention that might enhance the likelihood of successful implementation. The
18 transferability of the tailored intervention to other nursing homes might also be a
19 limitation.

1 Introduction

2 There remains an evidence-practice gap in preventing the risks of pressure ulcers,
3 malnutrition, poor oral health and falls among older persons in nursing homes^{1 2}. These health
4 risks cause a major burden for older persons³ and they are costly for the health care system⁴.
5 Since older persons are more vulnerable to these health risks⁵ and considering the increasing
6 ageing population globally, particularly with regard to older persons aged 80 years or older⁶,
7 evidence-based preventive work is crucial to manage this demographic challenge and,
8 importantly, these health risks among older persons.

9 In Sweden, there is a national quality register, Senior Alert, providing an individualized,
10 standardized, structured and systematic preventive care work process for older persons 65
11 years or older who are at risk of pressure ulcers, malnutrition, poor oral health and falls⁷.
12 Senior Alert provides evidence-based knowledge aimed at preventing these health risks to
13 enable a healthy ageing among older persons⁸; in addition, it can increase cost efficiency⁹.
14 However, a lack of knowledge among those working with older persons has been identified as
15 one major challenge regarding to preventive work^{2 10}. As a result, these health risks continue
16 to be prevalent⁷. For instance, approximately every third older person living in a nursing
17 home faces at least one of these health risks, and every tenth older person faces all four of
18 these health risks¹. Additionally, not all older persons who are at risk have planned care
19 interventions^{11 12} and there is a mismatch between identified risks and planned and performed
20 care interventions^{13 14}, thus indicating an evidence-practice gap and consequently,
21 highlighting the urgent need of translating knowledge into practice.

22 Nevertheless, this is not unique to Sweden or this context; in contrast, health systems
23 worldwide face the shared challenge of translating knowledge into practice¹⁵. Knowledge
24 translation has been defined as “*a dynamic and iterative process that includes synthesis,
25 dissemination, exchange and ethically sound application of knowledge to improve health care
26 of people in the country, provide more effective health service and products and strengthen
27 the health care system*”, p. 165¹⁶. Ineffective knowledge translation can result in an evidence-
28 practice gap¹⁷ and, worryingly, lead to situations in which patients are denied interventions
29 that have been proven to be beneficial¹⁸, which in turn can result in a reduction in their quality
30 of life¹⁹.

1 To bridge this evidence-practice gap, conceptual frameworks are recommended²⁰. The
2 knowledge-to-action (KTA) framework is intended to help the parties involved in the process
3 of knowledge translation¹⁸. The KTA framework is also appropriate when addressing an
4 evidence-practice gap¹⁵ and conducting pragmatic research¹⁸.

5 As a part of translating knowledge into practice and promoting knowledge use by end users²¹,
6 the engagement of both researchers and stakeholders in research is crucial²². Engaging
7 stakeholders at an early stage in the development of solutions that can be applied to real world
8 settings is essential according to the Medical Research Council's (MRC) framework for
9 complex interventions²³. Complex interventions have multiple components, target multiple
10 groups or levels of an organization and attempt to affect multiple outcomes²³. Additionally,
11 for complex interventions to be most useful to end users, the local context must be taken into
12 account²⁴. Since it is well underpinned that organizational factors hinder preventive work in
13 nursing homes^{2 25}, considering and understanding the local context and integrating it into the
14 process of intervention development is crucial²⁶.

15 Consequently, change in the practices of nursing homes is considered to be complex²⁷, but if
16 complex interventions are tailored to the local context²⁸, including the targets of the
17 intervention^{23 24} and is directly relevant to them²⁹, such interventions could be successful.

18 **Aim**

19 The aim of this study was to describe the development of a codesigned complex intervention
20 intended to prevent pressure ulcers, malnutrition, poor oral health and falls among older
21 persons in nursing homes.

22 **Methods**

23 **Definitions**

24 *Nursing homes* were defined based on the definition provided by Neziraj et al. (2021)¹:
25 residential care homes where older persons live and receive municipal health care.

26 Health care personnel and managers were defined based on the definition provided by Neziraj
27 et al. (2021) as follows²:

28 *Nurse aide*: a person with a secondary degree in nursing, involves three years of study in high
29 school *or* a person without any formal education in nursing.

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2
3 1 *Registered nurse*: a person with a bachelor's degree in nursing, which involves three years of
4 2 study at university.

5
6
7 3 *Manager*: a person who is in charge of nurse aides or registered nurses.

8
9 4 *End users*: nurse aides, registered nurses and managers working in nursing homes.

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11
12 5 *Stakeholders*: key persons working in the municipality who are considered to play an
13 6 important role in the development and implementation of the intervention.

14 15 16 7 **Study context and setting**

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18 8 In nursing homes, nurse aides are the main providers of care and services and are on duty
19 9 around the clock. Nurse aides work under the regulations of the Social and Services Act
20 10 (SFS)³⁰ but are also delegated tasks according to the Health and Medical Services Act
21 11 (HSL)³¹, usually by registered nurses. Registered nurses guide care in nursing homes and
22 12 work under the regulations of HSL³¹. In the current setting, a large town located in southern
23 13 Sweden with 39 nursing homes, one registered nurse (or occasionally more depending on the
24 14 size of the nursing home) is located in the nursing home during office hours but is also
25 15 available at any other time. Managers who are in charge of the care and services provided by
26 16 the nurse aides are located at their respective nursing homes during office hours.

27
28 17 For transparency, the research group (n=5) positions are reported; four of the researchers hold
29 18 positions as either doctoral students (MN), associated professors (MAX), professors (CK) or
30 19 senior lectures (PH) at the affiliated university. The last author (MA) is a PhD and hold the
31 20 position as a research and development coordinator in the municipality where the study was
32 21 conducted. All the authors are registered nurses, and two of them (MN, MA) specialize in
33 22 elderly care and have worked in this context previously,

34
35 23 In addition, a reference group was created, which consisted of experts (n=7) drawn from the
36 24 local context; nurse aide (n=1), managers in charge of nursing homes (n=2), head of managers
37 25 in charge of registered nurses (n=1), development managers (n=2) and head of the nursing
38 26 homes in the municipality (n=1).

39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 27 **Study design**

54
55 28 The current study describes the development of a codesigned complex intervention and is a
56 29 part of the PROSENIOR program (<https://mau.se/en/research/projects/prosenior/>). This part
57 30 of the PROSENIOR program aims to develop, test and evaluate a codesigned complex

1 intervention to prevent pressure ulcers, malnutrition, poor oral health and falls among older
2 persons living in nursing homes in a two-arm pragmatic cluster randomized trial. The
3 randomization was conducted with the double aim to first develop the intervention and then to
4 evaluate the feasibility in the nursing homes allocated to the intervention group. The current
5 study only reports on the intervention development part of this trial. The feasibility evaluation
6 regarding e.g. recruitment and retention of nursing homes and randomization procedure will
7 be reported separately elsewhere. In the current study, the randomization aimed to invite end
8 users allocated to the intervention arm to develop a codesigned complex intervention. The
9 control arm was therefore not included in the current study. The nursing home is the cluster
10 and the unit of allocation. The nursing homes were randomized using a computerized program
11 (Excel) by MN to either intervention or control arm. MN informed the managers in the
12 included nursing homes about allocation output. Due to the nature of the design, the cluster
13 randomization of nursing homes was unblinded to the nursing homes and the researchers
14 (Figure1).

15 The development of the codesigned complex intervention (hereafter called the intervention)
16 was conducted in three phases. The phases are described below. The development of the
17 current intervention was conducted in a pragmatic paradigm as it is intended to work in a real-
18 world setting²⁹; this process was inspired by the MRC guidelines for complex interventions²⁴,
19 applied the KTA framework¹⁸ and engaged end users and stakeholders in the process of
20 codesign³².

21 We follow the guidance for reporting intervention development studies (GUIDED)³³ when
22 describing the development of the intervention and the template for intervention description
23 and replication (TIDieR) checklist and guide³⁴ when describing the intervention. We use
24 “development” to refer to the whole process of intervention development and “design” to
25 indicate the intervention content, format and delivery.

26 **Patient and public involvement**

27 Patients or informal caregivers were not involved in the research process. End users
28 codesigned the intervention with the research group in workshops. Stakeholders were also
29 involved in this research; they supported the research group throughout the entire
30 development of the intervention by contributing their valuable knowledge. All engagement is
31 described in detail in the section “Development of the intervention” below.

1 **Development of the intervention**

2 We developed the intervention in three phases and applied the KTA framework in all phases
3 (Figure 2).

4 ***Theory***

5 The KTA framework takes implementation strategies into account already in the development
6 phase¹⁸, which promotes and sustains practice change¹⁵. We applied the KTA framework
7 because it offers a structured and systematic approach to translate knowledge into practice¹⁸.
8 It comprises two parts: knowledge creation and the action cycle. Since evidence-based
9 knowledge is already available to end users in the quality register Senior Alert, the action
10 cycle was applied during the development of the current intervention. The action cycle
11 consists of the following steps: *1. Identify the problem, identify and review selected*
12 *knowledge, 2. Adapt knowledge to the local context, 3. Assess barriers to knowledge use, 4.*
13 *Select and tailor implementation strategies, 5. Monitor knowledge use, 6. Evaluate the*
14 *outcomes and 7. Sustain knowledge use*^{18 35}. Steps 1-4 the action cycle were applied
15 throughout the development process of developing the intervention in an iterative, dynamic
16 and permeable way.

17 ***Phase one***

18 During this phase, we established contact with stakeholders in the municipality, updated us of
19 the current status of the literature in this area and conducted studies in the local context.

20 *Establishing contact with stakeholders in the municipality*

21 Initially, we established contact and met with the head of the nursing homes in the
22 municipality. The reference group was created in this phase (described in the paragraph
23 “Study context and setting” above).

24 *Searching for literature and conducting studies in the local context*

25 As a part of step 1 in the KTA framework, *identify the problem, identify and review selected*
26 *knowledge*, firstly, we updated us of the current status of the literature regarding prevention of
27 pressure ulcers, malnutrition, poor oral health and falls and intervention studies in this area.
28 Subsequently, we conducted a cross-sectional study to determine the prevalence of the risks
29 of pressure ulcers, malnutrition, poor oral health and falls in nursing homes in southern
30 Sweden¹.

1
2
3 1 As a part of steps 2-3 in the KTA framework, *adapt knowledge to the local context and assess*
4 *barriers to knowledge use*, we conducted focus group interviews (n=5) with end users (n=21)
5
6 2 who worked in nursing homes to prevent pressure ulcers, malnutrition, poor oral health and
7
8 3 falls². The focus group interviews lasted between 63 and 106 min (mean 83 min). A detailed
9
10 4 description of this study and its participants is provided in Neziraj et al². Additionally, we
11
12 5 asked the end users included in our previous study² how an optimal intervention could be
13
14 6 designed to prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among
15
16 7 older persons in nursing homes. These particular data were targeted for the current study.
17
18 8 Hence, these data were not reported in our previous study, but are included, analysed and
19
20 9 reported in our current study.

21 *Phase two*

22
23 12 During this phase, we recruited and randomized nursing homes. Subsequently, we invited end
24
25 13 users in the intervention arm to participate in workshops, and planned and conducted the
26
27 14 workshops. We also analysed the specific data regarding intervention design drawn from the
28
29 15 focus group interviews (see the previous paragraph on phase one for clarification) and the
30
31 16 workshops.

32 *Recruiting and randomizing nursing homes*

33
34
35 18 In this part of the two-arm pragmatic cluster randomized trial, randomization aimed to recruit
36
37 19 end users in nursing homes allocated to the intervention arm to codesign an intervention
38
39 20 together with the research group in workshops.

40
41 21 Inclusion criteria for the study were nursing homes working with and registered in the quality
42
43 22 register Senior Alert. We recruited eligible nursing homes (n=21) to participate in the study
44
45 23 via digital meetings. In total, eight nursing homes agreed to participate and were cluster
46
47 24 randomized using a computerized program to either the intervention (n=4) or control arm
48
49 25 (n=4). Subsequently, we invited end users (n=118) working in nursing homes in the
50
51 26 intervention arm to participate in workshops intended to develop a tailored intervention
52
53 27 together with the research group; the invitations were extended both via a digital information
54
55 28 video and in written form. The remaining end users (n=184) working in the nursing homes
56
57 29 who were allocated to the control arm continued with their usual care routine.

58 *Conducting workshops*

1
2
3 1 As a part of steps 2-4 in the KTA framework, *adapt knowledge to the local context, assess*
4 2 *barriers to knowledge use and select and tailor implementation strategies*, we conducted
5 3 workshops with end users. In total, four workshops were conducted, which featured two nurse
6 4 aides, one registered nurse and one manager in each workshop; the workshops were
7 5 conducted over the course of four weeks (March-April 2022). The workshops were kept small
8 6 to offer the end users the possibility of exhibiting activity and creativity³⁶. The first author
9 7 (MN) led the workshops together with one of the coauthors (all coauthors participated in one
10 8 workshop each). The workshops were intended to serve as a place in which participants could
11 9 learn together and discuss the design of the intervention in four different stations (Table 1).
12 10 The end users engaged in active discussion and wrote creative ideas and suggestions on the
13 11 walls and the board in a lecture hall designed for the purpose of encouraging creative
14 12 pedagogy. In the first station, the end users were asked to discuss the risks of pressure ulcers,
15 13 malnutrition, poor oral health and falls and the care interventions that should be applied. In
16 14 the second station, they were asked to discuss and identify barriers and facilitators they had
17 15 encountered in their own work regarding the preventive care process stipulated by Senior
18 16 Alert (identify a risk, assess causes and plan, undertake and evaluate care intervention).
19 17 Barriers were written down on pink post-it notes, while facilitators were written down on
20 18 green post-it notes. These post-it notes were subsequently placed at the appropriate location
21 19 on the board with regard to the predawn preventive care process. The focus of the discussions
22 20 at station three was on the end users' needs and the support they needed throughout the
23 21 preventive care process. In the fourth station, they were asked to discuss the core components
24 22 of the intervention, how to provide follow-ups and implementation strategies. After
25 23 completing each workshop, MN photographed and briefly summarized the written data from
26 24 each station. This summary was used if the end users in the subsequent workshop reached an
27 25 impasse and/or discussed and wrote similar suggestions and ideas to those proposed by the
28 26 end users in the previous workshop. Each workshop lasted for three hours, and the discussions
29 27 were audio recorded to support the written data collection during the analysis.

28

29

1 **Table 1.** Workshop content (n=4).

Workshop	Station	Content	Examples of questions to discuss
Workshop 1-4	Station 1	Case regarding an older person at risk of pressure ulcers, malnutrition, poor oral health and falls living in a nursing home	<ul style="list-style-type: none"> • What would you have done in this case regarding these four risks? • Are there any good examples? What can you learn from good examples? • What additional knowledge do you need regarding these four risks in order to produce a risk assessment and provide adequate care interventions?
	Station 2	Senior Alert's care process	<ul style="list-style-type: none"> • Place green/pink post-it notes on the care process regarding what works/what can be improved in your own work and workplace.
	Station 3	End users needs' and the support they need regarding preventive work	<ul style="list-style-type: none"> • What do you need in your preventive work? • Why is this important, and what is most important (rank 1-3)? • Who needs help in the context of preventive work? • Who should be involved and in what way? • What is necessary for it to be feasible? • How can you work better/smarter? • How can you work in a more sustainable way?
	Station 4	Core components of the intervention	<ul style="list-style-type: none"> • What should be included in the intervention? • Who should it target? • How should it be designed? • How much/often/for how long should the intervention take place? • How should it be followed up? • Where should it be implemented? • How should it be implemented?

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3 1 *Analysing the data from the focus group interviews and the workshops*

4
5 2 The analysis was guided by the six phases of reflexive thematic analysis described by Braun
6 and Clarke^{37 38}: 1. *Familiarizing with the data*, 2. *Coding*, 3. *Generating initial themes*, 4.
7
8 3 *Reviewing the identified themes*, 5. *Defining and naming the themes* and 6. *Producing the*
9
10 4 *report*. Thematic analysis was chosen because it facilitates a flexible analysis process but
11
12 5 simultaneously provides researchers with the core skills they need to conduct the analysis.
13

14 7 To familiarize ourselves with the data, MN and MA read the transcripts from the focus group
15
16 8 interviews, including the data specifically collected for the current study, and the written data
17
18 9 collected from the workshops. In addition, MN listened to all the audio-recorded discussions
19
20 10 from the workshops meticulously. During the process of reading the data, MN and MA
21
22 11 reflected on and generated initial codes. Subsequently, MN and MA met and discussed these
23
24 12 initial codes (1). Thereafter, MN and MA separately engaged in a process of identifying and
25
26 13 coding entities of interest in relation to the design of the intervention, giving equal attention to
27
28 14 all the data (2). The initial codes were then sorted into their core components in relation to the
29
30 15 design of the intervention (3). Next, the core components were reviewed by MN to determine
31
32 16 whether any relevant data regarding the design of the intervention had been missed (4).
33
34 17 Subsequently, MN designed an outline of the intervention. This outline contained the
35
36 18 intervention's proposed design, including its content, format, plan for delivery and duration.
37
38 19 In the following step of the analysis, the entire research group met and discussed the design of
39
40 20 the outline of the intervention. During this step, MN continuously revised the outline of the
41
42 21 intervention following discussions within the research group (5). Then, the outline of the
43
44 22 intervention was redesigned by MN. The redesigned outline of the intervention was then
45
46 23 presented to the research group before it was presented to the stakeholders. The process of
47
48 24 producing the final design of the intervention is described in phase three below (6).

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60
25 ***Phase three***

26 As part of steps 2-4 in the KTA framework, *adapt knowledge to the local context, assess*
27 *barriers to knowledge use and select and tailor implementation strategies*, MN and MA met
28 regularly with stakeholders in structured meetings to present and discuss the outline of the
29 intervention. MN documented all the meetings. MA works within the municipality and thus
30 facilitated contact with stakeholders who were considered to play an important role in this
31 part of designing the intervention. Since this part of the process was dynamic and iterative and
32 because all relevant uncertainties had not been addressed in the redesigned outline of the

1 intervention, it was helpful to meet stakeholders for the purpose of identifying and addressing
2 the remaining uncertainties regarding the content, format, delivery and duration of the
3 intervention. This part of the process was time-consuming and required a back-and-forth
4 process involving meetings and discussions between MN and MA, within the entire research
5 group and with the stakeholders. Next, the redesigned outline of the intervention was adjusted
6 by MN in accordance with the results of these meetings and discussions (Figure 3). Finally,
7 MN investigated whether any data from the focus group interviews and the workshops had
8 been missed, since these data were intended to serve as the foundation for designing the final
9 outline of the intervention. The final design of the intervention, the STAIR OF
10 KNOWLEDGE (Figure 4), is described below.

11 **Results**

12 Findings from our previous studies^{1 2} in phase one showed that the prevalence of the risk for
13 pressure ulcer, malnutrition, poor oral health and falls is still high in the local context.
14 Furthermore, findings from phase one suggested that individuals working with older persons
15 in nursing homes need increased knowledge concerning how to prevent these health risks.
16 Since existing evidence and knowledge concerning how to prevent these health risks is
17 already contained in Senior Alert, the challenge seems to lie in the evidence-practice gap.
18 Consequently, in phase two and three, a tailored intervention was codesigned with end users,
19 stakeholders and the research group to reduce the evidence-practice gap. The final design of
20 the intervention is presented below.

21 A majority of the end users (n=16) in workshops (n=4) were women (n=13), between the ages
22 of 28-63 years (mean 53), and had worked for 3-41 years (mean 18). The meetings (n=13)
23 with stakeholders (n=12) lasted between 60-180 min (mean 134 min).

24 **The final design of the intervention**

25 The final design of the intervention was described in line with the TIDieR checklist³⁴
26 (Supplementary file).

27 The STAIR OF KNOWLEDGE consists of *the foundation and stairs 1-6*, lasts for three
28 weeks and is divided into two parts. Part one, including *the foundation and stairs 1-5*, takes
29 place throughout the entire intervention period (weeks 1-3) and is delivered digitally to end
30 users in the nursing homes via their workplace email addresses. Part two includes *stair 6* and

1
2
3 1 takes place during the last week of the intervention period (week 3) in the nursing homes in
4
5 2 question (Figure 4).

7 3 **The content of the intervention**

9 4 *Part one of the intervention: the foundation and stairs 1-5*

11
12 5 End users emphasized uncertainties of different professionals' responsibilities regarding the
13
14 6 preventive work. For instance, they highlighted that it is highly relevant for respective
15
16 7 professional to know "who does what" regarding the preventive working. Hence, *the*
17
18 8 *foundation* is intended to facilitate for different professionals regarding responsibilities for
19
20 9 respective profession and working routine in the local context. *The foundation* provide end
21
22 10 users with knowledge and awareness of how to work preventively in the context of an existing
23
24 11 local working routine and is intended to represent "the ground to stand on".

25
26 12 Furthermore, end users expressed a need of increased knowledge regarding the health risks
27
28 13 and the entire preventive working process. They stressed the importance of basic knowledge
29
30 14 when working with older persons in nursing homes. According to end users, not all of them
31
32 15 has basic knowledge in how to prevent these health risks among older persons. This was
33
34 16 particularly common among temporary workers. To meet their need, *stairs 1-4* provide the
35
36 17 end users with general knowledge about risks of pressure ulcers, malnutrition, poor oral health
37
38 18 and falls according to the care process suggested by the quality register Senior Alert (*stair 1*),
39
40 19 risk assessment instruments (*stair 2*), the underlying causes of these risks (*stair 3*) and
41
42 20 preventive care interventions (*stair 4*). *Stairs 1-5* provide end users with website links that
43
44 21 allow them to both read texts and watch videos. *Stairs 1-4* are mandatory for all professionals.
45
46 22 *Stair 5* provides end users with knowledge of how to register in the quality register Senior
47
48 23 Alert and is mandatory only for users who have access to and the responsibility to register in
49
50 24 the quality register Senior Alert.

51 25 *Part two of the intervention: stair 6*

52
53 26 Although it was necessary for end users to increase their knowledge on their own regarding
54
55 27 the preventive work, they particularly highlighted the importance of physical meetings. This
56
57 28 was also stressed as important by stakeholders and was considered as a complement to the
58
59 29 first part of the intervention. Therefore, in part two, *stair 6*, a facilitator (MN) meets with end
60
30 users to interact with them and discuss the knowledge acquired during part one. The meetings
31
32 will be structured including discussions based on different cases related to pressure ulcers,

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2
3 1 malnutrition, poor oral health and falls. End users will also perform risk assessments, identify
4 the underlying causes and plan accurate care interventions based on these cases. Additionally,
5 2 the underlying causes and plan accurate care interventions based on these cases. Additionally,
6 3 end users will identify environmental risk factors related to the risks of pressure ulcers,
7 4 malnutrition, poor oral health and falls in their own workplace. They will also discuss and
8 5 generate ideas how to follow up on the preventive care process on an organizational level.
9 6 This part of the intervention is intended to inspire end users to prevent pressure ulcers,
10 7 malnutrition, poor oral health and falls among older persons in nursing homes.

8 **The format of the intervention**

9 *Part one of the intervention: the foundation and stairs 1-5*

10 From end users' perspective, it was important with a clear format. They expressed a need of a
11 structured, readable and colourful working "manual". Hence, the format of the intervention is
12 designed as colourful stair with the intention to visualize the entire preventive working
13 process. To enhance the structure, end users are provided with written instructions in
14 respective stair. Furthermore, stakeholder emphasized the need of a "self-check box" for end
15 users when completing the foundation and stairs in the intervention. Stakeholder believed that
16 this could increase participation and involvement among end users. Since both end users and
17 stakeholders stressed that there are many end users that do not have the Swedish language as
18 their native language, the language is adjusted to suit the local context. Furthermore, end users
19 expressed that the format of the intervention should consider different ways of learning. This
20 was also highlighted as important by stakeholders. Hence, the format consist of both reading
21 texts and watching videos. Moreover, end users and stakeholders emphasized that a digital
22 intervention could be a sustainable solution.

23 *Part two of the intervention: stair 6*

24 End users and stakeholder were in agreement that it is necessary to meet and discuss.
25 Therefore, in part two of the intervention, end users meet in their respective nursing home.
26 Also, the format of this part of the intervention was designed as an inspiration to raise
27 awareness of the preventive work among end users.

28 **The delivery of the intervention**

29 *Part one of the intervention: the foundation and stairs 1-5*

1
2
3 1 The intervention will be delivered via email to managers in nursing homes. Subsequently,
4
5 2 respective manager will forward the intervention via workplace email addresses to nurse aides
6
7 3 and registered nurses. The end users highlighted that some learn better individually while
8
9 4 others learn better in group. Therefore, they are permitted to choose if they want to read texts
10
11 5 and watch videos individually and/or in group. *The foundation and stairs 1-5* is anticipated to
12
13 6 take approximately 10 minutes, 60 minutes, 20 minutes, 10 minutes, 30 minutes and 60
14
15 7 minutes respectively for end users to complete. End users can choose to complete this part of
16
17 8 intervention at once or divide it during working hours.

17
18 9 *Part two of the intervention: stair 6*

19
20 10 Part two of the intervention will be delivered by a facilitator (MN) who will moderate
21
22 11 sessions lasting approximately 30 minutes each, Monday-Friday, in the nursing homes in
23
24 12 question. If end users participate in all the sessions during this week, the planned amount of
25
26 13 time is two and half hours for each end user.

27
28 14 **Discussion**

29
30 15 The current codesigned complex intervention, the STAIR OF KNOWLEDGE, was developed
31
32 16 together with end users in workshops in an active and creative way. Stakeholders were also
33
34 17 engaged in an iterative and dynamic way throughout the development of the intervention, as
35
36 18 an important part of undertaking implementation strategies already in the development
37
38 19 phase³⁹. As recommended by the MRC framework²⁴, we meticulously considered the
39
40 20 relationship between the intervention and its context when developing the intervention.
41
42 21 Furthermore, we followed the strategies for knowledge translation included in the KTA
43
44 22 framework¹⁸. Hence, the strengths exhibited by the development of this complex intervention
45
46 23 lie in the fact that it was developed both together with and for end users and engaged
47
48 24 stakeholders who are considered to play an important role in the development and
49
50 25 implementation process. The current intervention is intended to work in a real-world setting
51
52 26 and aims to bridge the evidence-practice gap regarding the process of preventing the risks of
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54 27 pressure ulcers, malnutrition, poor oral health and falls; ultimately, this intervention may
55
56 28 reduce these risks among older persons in nursing homes.

57
58 29 When developing new intervention, the value of the used design process cannot be
59
60 30 understated⁴⁰. In fact, engagement of end users in a creative environment have been linked to
31
32 31 more robust research and development efforts, which in turn may drive more successful

1 interventions outcome⁴⁰. Hence, the benefits of codesign are potentially substantial⁴¹. For
2 instance, engaging end users and stakeholders as design partners to the research group could
3 ensure that the intervention exhibits a better fit to their needs³². Engaging end users and
4 stakeholders early enables their experiences and requirements to be taken into account at the
5 start rather than a situation in which the researchers presume to know what is required³⁹. In
6 the current development process, although end users' and stakeholders' engagement ranged in
7 intensity from relatively passive to highly active, their engagement pervaded the entire
8 development process, and important decisions regarding the intervention design were made
9 by considering their input. Furthermore, because we engaged end users and stakeholders, the
10 current intervention was based on their own experiences regarding the evidence and
11 knowledge that are necessary throughout the entire process of preventing the risks of pressure
12 ulcers, malnutrition, poor oral health and falls. Engaging end users and stakeholders during
13 the developing process⁴² was also important in light of the local context since this enabled us
14 to identify facilitators and barriers in the environment in which the intervention will
15 eventually be implemented²⁶.

16 A recent scoping review investigating education interventions for health professionals on fall
17 prevention in health care settings⁴³, highlighted that health professional education to prevent
18 fall is important. Nevertheless, the scoping review concluded that there are no uniform
19 education design principles utilized to date⁴³. Another review found that it was uncertain
20 whether education delivered in different format such as didactic or video-based format makes
21 a difference to health professionals' knowledge of pressure ulcers prevention. However,
22 education format in the current developed intervention was designed to fit end users' needs
23 and suit the local context, which may have benefits for the outcome.

24 Considering and understanding the local context is also crucial when addressing an evidence-
25 practice gap²⁴. In this case, knowledge concerning the process of preventing the risks of
26 pressure ulcers, malnutrition, poor oral health and falls is already contained in the quality
27 register Senior Alert, but this evidence has not been fully translated into practice. Thus, we
28 focused on translating the existing knowledge contained in Senior Alert into practice.
29 However, if this knowledge is to be implemented effectively⁴⁴, it is crucial to employ a
30 conceptual framework²⁰. Therefore, we chose the KTA framework because it provided us
31 with knowledge translation strategies to reduce the evidence-practice gap¹⁸, and it was
32 suitable since the quality register Senior Alert is already in use. Furthermore, adapting

1
2
3 1 knowledge to the local context and assessing barriers to knowledge use may enable the
4
5 2 research to have a greater impact⁴⁵, which could in turn reduce the evidence-practice gap.
6
7 3 Successful intervention development is characterized as rigorous and scientific and leads to an
8
9 4 intervention that can be implemented in a real-world setting³³. The robust research process
10
11 5 used to develop the STAIR OF KNOWLEDGE intervention incorporates existing evidence,
12
13 6 the views of end users and stakeholders⁴¹, the local context and knowledge translation
14
15 7 strategies. Consequently, the use of knowledge translation strategies and the engagement of
16
17 8 end users who are embedded in the local context in the development of a tailored complex
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19 9 intervention both for and with them could contribute to increased knowledge and awareness
20
21 10 of the entire process of preventive care. This may, in turn, reduce the evidence-practice gap
22
23 11 among end users and, importantly, reduce the risk of pressure ulcers, malnutrition, poor oral
24
25 12 health and falls among older persons in nursing homes. Furthermore, the engagement of
26
27 13 stakeholders already in the development process is likely to facilitate the implementation of
28
29 14 the current intervention.

30 **Limitations**

31
32 16 Although the development of this complex intervention has been completed, it is important to
33
34 17 acknowledge the limitations of the development process. First, only four clusters were
35
36 18 included in the development process. Nevertheless, since this part of the trial focused on the
37
38 19 development of an intervention rather than its evaluation and because the clusters were
39
40 20 recruited pragmatically, the clusters included in the trial could be considered sufficient.
41
42 21 Second, although all end users in the intervention arm (n=118) were invited to participate in
43
44 22 workshops, only 16 participated. However, different professionals participated in the
45
46 23 workshops, and the discussions were energetic, active and creative. Third, although this
47
48 24 design is creative and can generate new ideas, it is time- and resource-consuming for all parties
49
50 25 involved. It requires end users and stakeholders to set aside time and expend extra effort in
51
52 26 their daily work. For researchers, this process requires careful planning to enable them to
53
54 27 coordinate, meet with many different persons repeatedly and be responsive to all parties
55
56 28 involved. However, although this design required the expenditure of time and resources, the
57
58 29 engagement of end users, stakeholders and researchers is meaningful and necessary to
59
60 30 develop successful interventions; ultimately, this design might have an impact on to prevent
31 the risks of pressure ulcers, malnutrition, poor oral health and falls among older persons in

1 nursing homes. Furthermore, the current intervention might offer value when used by others
2 and could likely be adjusted to and tested in similar contexts.

3 **Conclusion**

4 The current codesign complex intervention, the STAIR OF KNOWLEDGE, which aims to
5 prevent the risks of pressure ulcers, malnutrition, poor oral health and falls among older
6 persons in nursing homes, is robustly developed and thoroughly described. A careful
7 description of the entire development process and the intervention itself can enhance the
8 replicability of the current intervention. This article highlights the extensive process that is
9 necessary for the development of tailored complex interventions. Finally, this codesigned
10 complex intervention might result in more evidence-based practice concerning the entire
11 process of preventing the risks of pressure ulcers, malnutrition, poor oral health and falls and,
12 importantly, reduce these health risks among older persons in nursing homes. However,
13 uncertainties regarding the intervention itself remain. Thus, the STAIR OF KNOWLEDGE
14 must be tested and evaluated in an upcoming feasibility study before we continue to the stage
15 of conducting a full trial evaluation.

16 **Ethical considerations**

17 This trial was approved by the Swedish Ethical Review Authority (DNR 2019-06414). In
18 addition, written approval was requested and granted by the head of the department of elderly
19 care homes in the municipality in which this trial was conducted. All end users working in
20 eligible nursing homes were invited to participate in the workshops. Moreover, end users had
21 the right to withdraw from participation at any stage without providing reasons and bearing
22 any consequences. Participation in the workshops was based on written consent. The results
23 of this trial may be considered to contribute to scientific value on good ethical grounds, and
24 the benefits of participating in the trial outweigh the corresponding risks.

25 **Funding statement**

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28 research manuscript's design, conduct, analysis, interpretation or drafting.

29 **CRediT authorship contribution statement**

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3 1 **Merita Neziraj:** Conceptualization, Methodology, Investigation, Writing – original draft,
4 Writing – review & editing, Validation, Formal analysis, Visualization. **Malin Axelsson:**
5 2 Conceptualization, Methodology, Investigation, Writing – review & editing, Validation,
6 3 Supervision. **Christine Kumlien:** Conceptualization, Methodology, Investigation, Writing –
7 4 review & editing, Validation, Supervision. **Peter Hellman:** Conceptualization, Methodology,
8 5 Investigation, Writing – review & editing, Validation, Supervision. **Magdalena Andersson:**
9 6 Conceptualization, Methodology, Investigation, Writing – review & editing, Validation,
10 7 Formal analysis, Supervision. All the authors read and approved the final version of the
11 8 manuscript.
12 9

10 **Competing interests**

11 The authors have no conflicts of interest.

12 **Participant consent**

13 All participation in the workshops was based on written consent.

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18 KNOWLEDGE intervention. The Derbring and Stölten foundation is acknowledged for its
19 financial support.

20 **Data sharing statement**

21 The data that support the development of the STAIR OF KNOWLEDGE intervention are not
22 publicly available to ensure confidentiality. All data relevant to the development are included
23 in the article. All figures and tables included in this article are original.

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30 Figure 1 – Flowchart of the two-arm pragmatic cluster randomized controlled trial. The dashed lines
31 illustrate an upcoming study. The current study focused on the development of the STAIR OF
32 KNOWLEDGE intervention.

33 Figure 2 - Phases one-three illustrate the process of developing the STAIR OF KNOWLEDGE
34 intervention, which took place between 2019 and 2022. Although the knowledge-to-action (KTA)
35 framework is viewed as a cycle by Graham and colleagues (2006), in this figure, the arrow illustrates
36 the fact that the KTA framework was applied throughout phases one-three of the development
37 process. The KTA framework was applied in an iterative and dynamic way in each phase and is
38 described in detail in the text.

39 Figure 3 - Note: T=how long the meeting lasted for, reported in minutes. MN=the first author.
40 MA=the last author.

41 The iterative and dynamic process of designing the final outline of the STAIR OF KNOWLEDGE
42 intervention between April and September 2022, including meetings and discussions with
43 stakeholders. In all the meetings, the first author participated. In addition, in some meetings also the
44 last author participated. The blue arrows illustrate that adjustments were made following each
45 meeting.

46 Figure 4 - Final design of the STAIR OF KNOWLEDGE intervention.

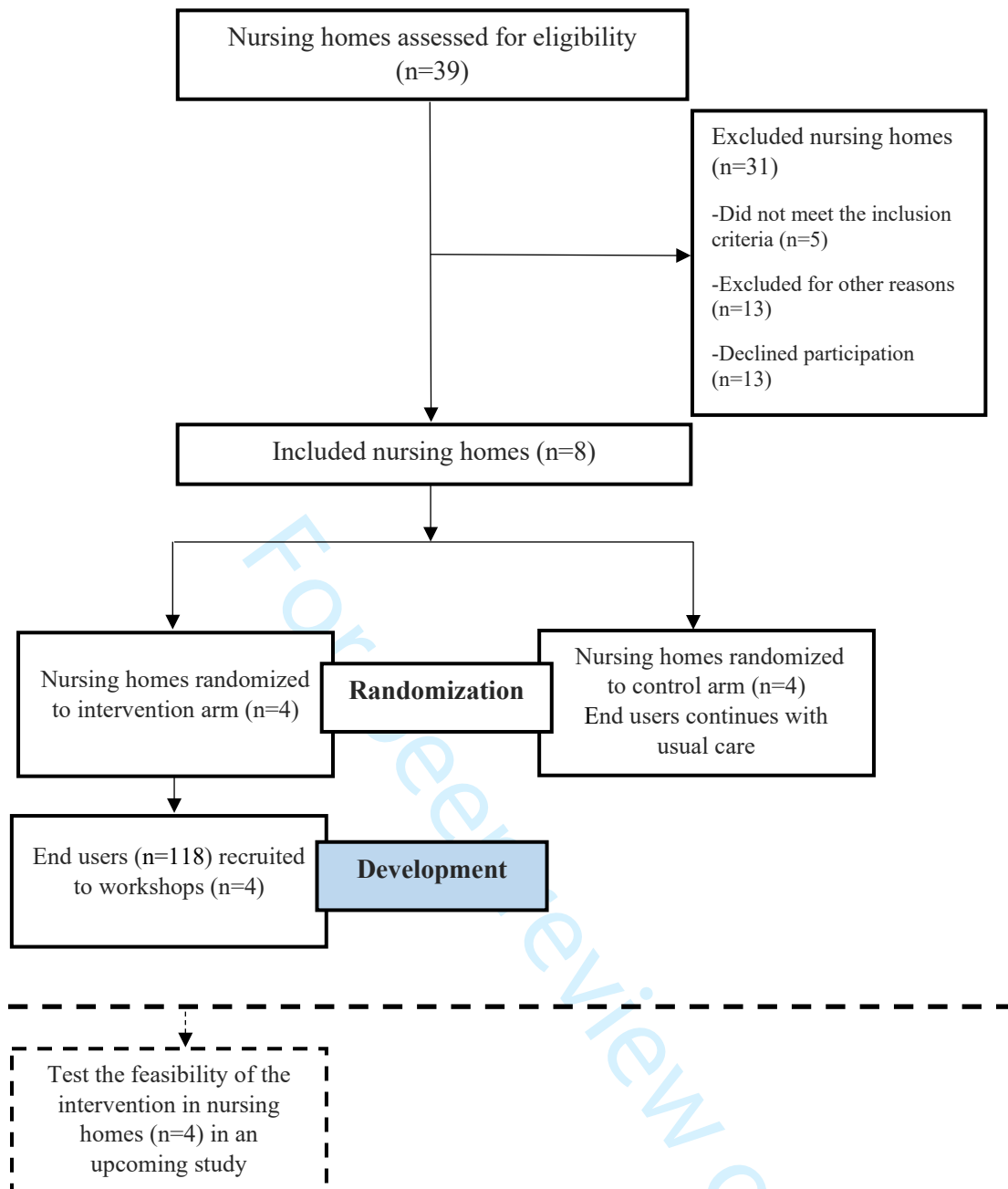


Figure 1. Flowchart of the two-arm pragmatic cluster randomized controlled trial. The dashed lines illustrate an upcoming study. The current study focused on the development of the STAIR OF KNOWLEDGE intervention.

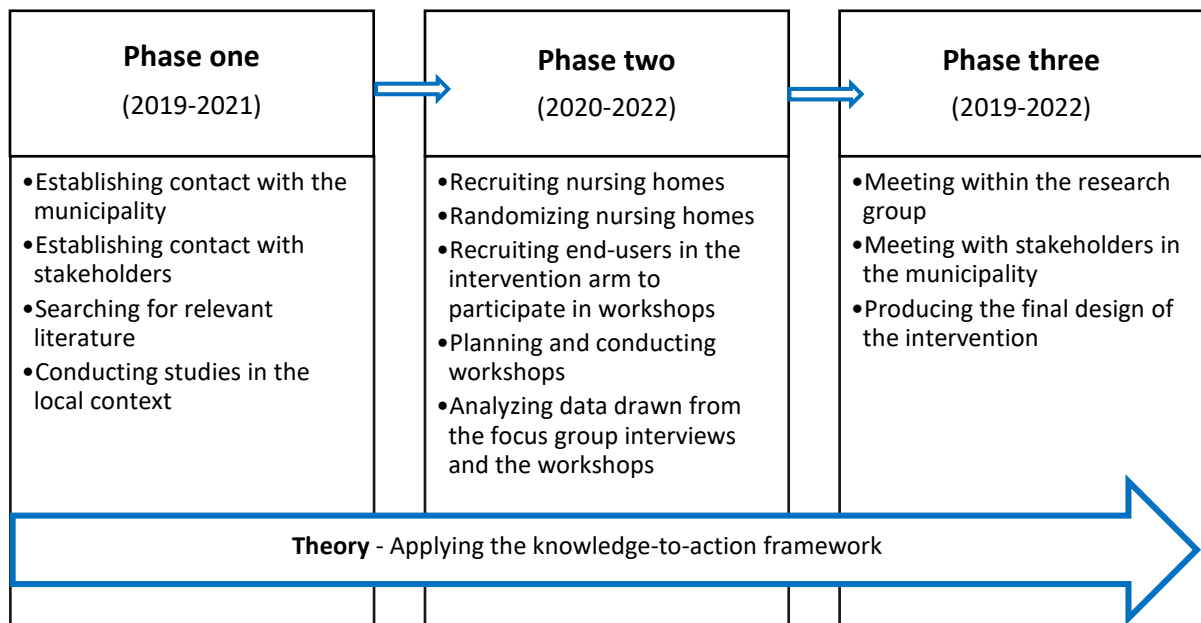


Figure 2. Phases one-three illustrate the process of developing the STAIR OF KNOWLEDGE intervention, which took place between 2019 and 2022. Although the knowledge-to-action (KTA) framework is viewed as a cycle by Graham and colleagues (2006), in this figure, the arrow illustrates the fact that the KTA framework was applied throughout phases one-three of the development process. The KTA framework was applied in an iterative and dynamic way in each phase and is described in detail in the text.

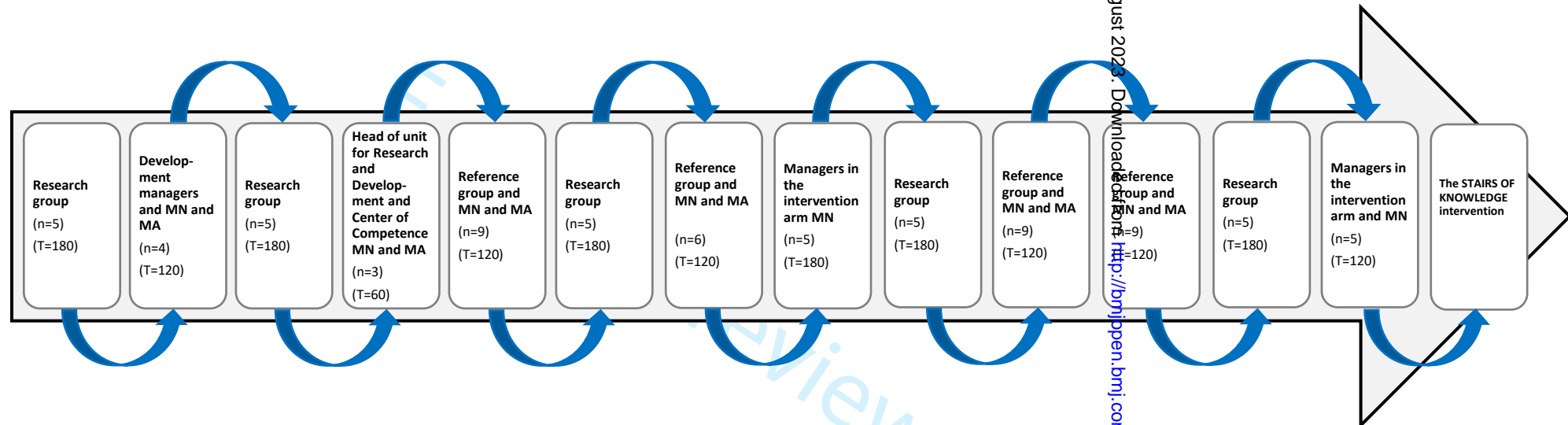
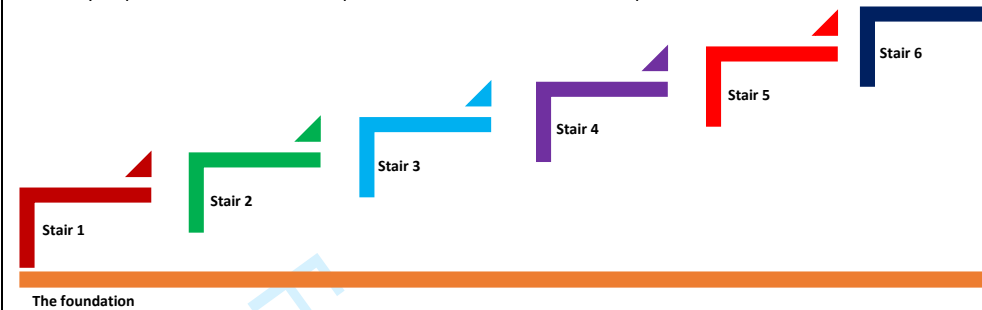


Figure 3. Note: T=how long the meeting lasted for, reported in minutes. MN=the first author. MA=the last author. The iterative and dynamic process of designing the final outline of the STAIR OF KNOWLEDGE intervention between April and September 2022, including meetings and discussions with stakeholders. In all the meetings, the first author participated. In addition, in some meetings also the last author participated. The blue arrows illustrate that adjustments were made following each meeting.

The STAIR OF KNOWLEDGE

The STAIR OF KNOWLEDGE is addressed to all nurse aides, registered nurses and managers who work with older persons in nursing homes. The STAIR OF KNOWLEDGE aims to increase knowledge regarding the preventive care necessary to prevent the risks of falls, pressure ulcers, malnutrition and poor oral health.



The foundation is mandatory for nurse aides, registered nurses and managers. **Stairs 1-4** and **stair 6** are mandatory for all nurse aides, registered nurses and managers. **Stair 5** is mandatory for individuals who register in Senior Alert. Follow the instructions below.

For your convenience, click the boxes as you progress through the STAIR OF KNOWLEDGE.

- | | | | |
|------------|--------------------------|------------|--------------------------|
| Foundation | <input type="checkbox"/> | Stair 4a-d | <input type="checkbox"/> |
| Stair 1a-d | <input type="checkbox"/> | Stair 5 | <input type="checkbox"/> |
| Stair 2a-d | <input type="checkbox"/> | Stair 6 | <input type="checkbox"/> |
| Stair 3 | <input type="checkbox"/> | | |

The foundation. Local working description of the entire preventive care working process.

- Link to the local working routine.

Stair 1a-d. General information regarding falls, pressure ulcers, malnutrition and poor oral health.

- Links to texts and videos regarding falls, pressure ulcers, malnutrition and poor oral health.

Stair 2a-d. Risk assessment of falls, pressure ulcers, malnutrition and poor oral health.

- Links to texts and videos regarding the risk assessment of falls, pressure ulcers, malnutrition and poor oral health.

Stair 3. Causes of falls, pressure ulcers, malnutrition and poor oral health.

- Link to text regarding the causes of falls, pressure ulcers, malnutrition and poor oral health.

Stair 4a-d. Preventive care interventions for falls, pressure ulcers, malnutrition and poor oral health.

- Links to texts regarding preventive care interventions for falls, pressure ulcers, malnutrition and poor oral health.

Stair 5. Registering in Senior Alert.

- Links to texts and videos regarding how to register in Senior Alert.

Stair 6. Inspiration week.

- Inspiration week focuses on preventive care intended to prevent the risks of falls, pressure ulcers, malnutrition and poor oral health in an inspiring and motivating way. The inspiration week will be organized by and for employees and managers. The inspiration week is preferably organized twice per year.

Figure 4. Final design of the STAIR OF KNOWLEDGE intervention.



Template for Intervention
Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME	p. 1	
1.	Provide the name or a phrase that describes the intervention.		
	WHY	p. 4-4 +- 6-8	
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.		
	WHAT	p. 13-16	
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	p. 13-16	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.		
	WHO PROVIDED	p. 5 + 13 + Figure 4	
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.		
	HOW	p. 13-16	
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.		
	WHERE	p. 13-16	

7. Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.

WHEN and HOW MUCH

8. Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.

TAILORING

9. If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.

MODIFICATIONS

10.* If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).

HOW WELL

11. Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.

12.* Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.

P. 13-16

P. 13-16

N/A

N/A

N/A

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the

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1 TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement**.
 2 When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013**
 3 **Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see
 4 www.equator-network.org).
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For peer review only

GUIDED – a guideline for reporting for intervention development studies.

Supplementary File 1: Blank Checklist

Item description	Explanation	Page in manuscript where item is located	Other*
1. Report the context for which the intervention was developed.	Understanding the context in which an intervention was developed informs readers about the suitability and transferability of the intervention to the context in which they are considering evaluating, adapting or using the intervention. Context here can include place, organisational and wider socio-political factors that may influence the development and/or delivery of the intervention (15).	Page 5 (Study context)	
2. Report the purpose of the intervention development process.	Clearly describing the purpose of the intervention specifies what it sets out to achieve. The purpose may be informed by research priorities, for example those identified in systematic reviews, evidence gaps set out in practice guidance such as The National Institute for Health and Care Excellence or specific prioritisation exercises such as those undertaken with patients and practitioners through the James Lind Alliance.	Page 4-5 (Introduction) Page 8-13 Development of the intervention)	
3. Report the target population for the intervention development process.	The target population is the population that will potentially benefit from the intervention – this may include patients, clinicians, and/or members of the public. If the target population is clearly described then readers will be able to understand the relevance of the intervention to their own research or practice. Health inequalities, gender and ethnicity are features of the target population that may be relevant to intervention development processes.	Page 8-13 (Development of the intervention) Page 13 (Results)	
4. Report how any published intervention development approach contributed to the development process	Many formal intervention development approaches exist and are used to guide the intervention development process (e.g. 6Squid (16) or The Person Based Approach to Intervention Development (17)). Where a formal intervention development approach is used, it is helpful to describe the process that was followed, including any deviations. More general approaches to intervention development also exist and have been categorised as follows (3):- Target Population-centred intervention development; evidence and theory-based intervention development; partnership intervention development; implementation-based intervention development; efficacy-based intervention development; step or phased-based intervention development; and intervention-specific intervention development (3). These approaches do not always have specific guidance that describe their use. Nevertheless, it is helpful to give a rich description of how any published approach was operationalised	Page 4-5 (Introduction) Page 6 (Study design)	
5. Report how evidence from different sources informed the intervention development process.	Intervention development is often based on published evidence and/or primary data that has been collected to inform the intervention development process. It is useful to describe and reference all forms of evidence and data that have informed the development of the intervention because evidence bases can change rapidly, and to explain the manner in which the evidence and/or data was used. Understanding what evidence was and was not available at the time of intervention development can help readers to assess transferability to their current situation.	Page 8-13 (Development of the intervention)	
6. Report how/if published theory informed the intervention development process.	Reporting whether and how theory informed the intervention development process aids the reader's understanding of the theoretical rationale that underpins the intervention. Though not mentioned in the e-Delphi or consensus meeting, it became increasingly apparent through the development of our guidance that this theory item could relate to either existing published theory or programme theory	Page 4-5 (Introduction) Page 6 (Study design) Page 7 (Theory)	
7. Report any use of components from an existing intervention in the current intervention development process.	Some interventions are developed with components that have been adopted from existing interventions. Clearly identifying components that have been adopted or adapted and acknowledging their original source helps the reader to understand and distinguish between the novel and adopted components of the new intervention.	The intervention is based on existing evidence-based knowledge in Senior Alert. See figure 4.	
8. Report any guiding principles, people or factors that were prioritised when making decisions during the intervention development process.	Reporting any guiding principles that governed the development of the application helps the reader to understand the authors' reasoning behind the decisions that were made. These could include the examples of particular populations who views are being considered when designing the intervention, the modality that is viewed as being most appropriate, design features considered important for the target population, or the potential for the intervention to be scaled up.	Page 6-10 (Development of the intervention)	

Item description	Explanation	Page in manuscript where item is located	Other*
9. Report how stakeholders contributed to the intervention development process.	Potential stakeholders can include patient and community representatives, local and national policy makers, health care providers and those paying for or commissioning health care. Each of these groups may influence the intervention development process in different ways. Specifying how differing groups of stakeholders contributed to the intervention development process helps the reader to understand how stakeholders were involved and the degree of influence they had on the overall process. Further detail on how to integrate stakeholder contributions within intervention reporting are available (19).	Page 8-13 (Development of the intervention)	
10. Report how the intervention changed in content and format from the start of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	Page 12 (Analysed the data from the focus group interviews and workshops) + Page 12 (Third phase)	
11. Report any changes to interventions required or likely to be required for subgroups.	Specifying any changes that the intervention development team perceive are required for the intervention to be delivered or tailored to specific sub groups enables readers to understand the applicability of the intervention to their target population or context. These changes could include changes to personnel delivering the intervention, to the content of the intervention, or to the mode of delivery of the intervention.	Page 12 (Analysed the data from the focus group interviews and workshops) + Page 12 (Third phase) + Page 13 (Results)	
12. Report important uncertainties at the end of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	Page 11-12 (Discussion)	
13. Follow TIDieR guidance when describing the developed intervention.	Interventions have been poorly reported for a number of years. In response to this, internationally recognized guidance has been published to support the high quality reporting of health care? interventions ⁵ and public health interventions ¹⁴ . This guidance should therefore be followed when describing a developed intervention.	The description of the intervention follows TIDieR	
14. Report the intervention development process in an open access format.	Unless reports of intervention development are available people considering using an intervention cannot understand the process that was undertaken and make a judgement about its appropriateness to their context. It also limits cumulative learning about intervention development methodology and observed consequences at later evaluation, translation and implementation stages. Reporting intervention development in an open access (Gold or Green) publishing format increases the accessibility and visibility of intervention development research and makes it more likely to be read and used. Potential platforms for open access publication of intervention development include open access journal publications, freely accessible funder reports or a study web-page that details the intervention development process.	Submitted to the BMJ Open	

*e.g. if item is reported elsewhere, then the location of this information can be stated here.