BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-060314
Article Type:	Protocol
Date Submitted by the Author:	20-Dec-2021
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Keywords:	EDUCATION & TRAINING (see Medical Education & Training), GERIATRIC MEDICINE, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, MEDICAL EDUCATION & TRAINING

The Responding to Elder Abuse in GERiAtric care (REAGERA) educational intervention for health care professionals. A non-randomised stepped wedge trial.

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Key Words

Elder abuse, Medical education, Forum Play, Forum Theatre

Word count: 3506

Abstract

Introduction

Elder abuse is prevalent, and is associated with different forms of ill health. Despite this, health care providers are often unaware of abusive experiences among older patients and many lack training about elder abuse. The overall aim of the study described in this protocol is to increase health care professionals' propensity to ask older patients questions about abusive experiences.

Methods and analysis

Approximately 800 health care professionals at different hospital clinics and primary health care centres in Sweden will undergo a full-day training session on elder abuse. The design is a non-randomised stepped wedge trial in which all participants gradually transit from control group to intervention group. The training consists of three different parts: 1) Theory and group discussions: What is elder abuse? How can it be detected and what are the options for handling cases? 2) Forum play: A form of participatory theatre in which participants are given the opportunity to practise how to manage difficult patient encounters and find alternative ways of acting, even in situations that may initially feel challenging. 3) Post-training reflection on changing practices.

Ethics and dissemination

The study has been approved by the Swedish Ethical Review Authority (reference no. 2020-02548). The results will be published in peer-reviewed journals and conference proceedings. If the intervention is successful, a training manual will also be published. The purpose is to use this manual to disseminate the training to other clinics or organisations that wish to use it.

Registration

This trial is registered at clinicaltrials.gov (ID no. NCT05065281).

Strengths and limitations of this study

- This study includes a large cohort (n=800) of health care professionals who will undergo training about how to detect and respond to elder abuse.
- The training combines theory with forum play – a form of participatory theatre – and together this will stimulate embodied knowledge that is transferrable to everyday practice.
- The stepped wedge design provides an opportunity to assess how time affects the impact of the training and to investigate cluster effects, i.e., how factors on the clinical level impact the results.

- The outcome of the training will be measured using both self-reported data from participants and statistics from medical records concerning whether more patients with abusive histories are identified post-intervention.

Introduction

Past year prevalence of elder abuse in community samples is reported to be around 10-15% (1, 2). Studies conducted among the most vulnerable older adults, e.g., those residing in nursing homes or suffering from cognitive impairment, often report much higher prevalence rates, around 30-60% (2, 3). In this study, we use the WHO definition of elder abuse, including physical, psychological, sexual and economical abuse, as well as neglect occurring in any relationship where there is an expectation of trust, e.g., relatives as well as health and social care staff (2, 4, 5). Elder abuse is associated with mental ill health, physical disability, an increased number of hospitalisations and an increased need to move into assisted living (2, 5-7). Despite the high prevalence of elder abuse and strong associations with ill health, older adults' exposure to abuse is often unknown to caregivers. This study protocol describes an educational intervention aiming to train health care professionals to better identify and help older patients who are or have previously been subjected to abuse.

Many older adults who are exposed to abuse report that they need more help than they are currently receiving (8). Despite this, victims are reluctant to seek help (9, 10). Feelings of shame are reported, and many older adults do not know where to turn for help (11, 12). The health care system is considered to be an important place for identifying victims of elder abuse (7, 13). However, in a previous Swedish population study, one in four respondents over the age of 65 reported that they had been subjected to abuse at some point in their life, but only 7% of victims remembered ever being asked questions about abusive experiences by health care professionals (14). Also, research indicates that health care staff are often insufficiently prepared to detect and manage cases of elder abuse (7, 15). In line with this, we previously found that only 22% of the staff at an internal medicine and geriatric clinic in Sweden rated preparedness for taking care of victims of elder abuse at their own clinic as very or fairly good, while 42% did not know about this preparedness and 36% rated preparedness as very or somewhat inadequate (16).

It is difficult to detect and determine the symptoms of abuse. This difficulty particularly applies to older adults whose medical conditions may mask signs of abuse. For example, many older adults have an increased tendency to bruise as a result of medical treatment, and it is also common to have an increased risk of falling and injuries after falls. Thus, there is an obvious risk of caregivers not interpreting injuries as a sign of abuse, and also of suspecting that the patient's injuries are due to abuse even when they are not (10, 17). In addition, most common physical signs of abuse are absent, and staff need to be attentive to other signs, such as psychological symptoms or social problems. However, such symptoms might also be absent or difficult to detect. Considering the complexity of the issue, staff need education and training about elder abuse. However, in the aforementioned study among health care professionals at an internal medicine and geriatric clinic, only 27% of staff

had received any form of training regarding elder abuse. A further 26% had received training about violence in close relationships. However, 48% reported that they had received no training regarding violence and abuse at all, or that they did not remember whether they had received any such training. Having received training was, however, associated with a greater likelihood of reporting experiences of speaking with an older patient about abuse (16).

There have been relatively few studies of effective ways to train staff about elder abuse. The few studies that have been conducted do show that it is not effective to only hand out information material to staff (18). Rather, interactive training components have been recommended (19). Using patient cases and practical training with real or simulated patients or through virtual reality (VR) has been appreciated by participants (18, 20, 21). It has also previously been highlighted that training should be adapted to local conditions. Being able to give contact details to relevant local organisations for victims is important, so that the training can easily be translated into everyday practice (18).

In this project, health care professionals will be trained to ask older patients questions about abuse and to better manage the response. The education consists of theory and group discussions as well as forum play, a form of interactive theatre where participants – together with drama teachers – practise dealing with difficult situations and finding alternative ways of acting, as a form of skills training. Forum play has been described as an innovative training model that stimulates reflection and learning within the health care system (22). The method has previously been used for purposes such as training health care staff to counter abuse in health care (22, 23). A pilot study of the proposed training model has been carried out previously, with positive results which will be published separately.

Aim

The overall aim of the project is to increase health care professionals' propensity to ask older patients questions about abusive experiences. More specifically, we will:

1) Investigate whether the training changes the propensity to ask questions about abuse.
2) Investigate whether the training changes a) participants' self-efficacy concerning their own ability to ask questions about abuse and to manage the response, and b) participants' perceived barriers to asking questions on an individual or organisational level.

Method and analysis

Design

The design is a non-randomised stepped wedge trial, a type of controlled cohort study in which the participants gradually move from control group to intervention group (24, 25). At the end of the study all participants will have completed the intervention, i.e., participated in the training. See Figure 1 for a schematic overview of the study design. The stepped wedge design is generally recommended when an intervention is expected to do more good than harm and when, for logistical or practical reasons, it is impossible to implement the intervention for all participants simultaneously. Both of these circumstances apply to our planned study. The design also provides opportunities to investigate how time affects the impact of an intervention, which is why the design is often used when it is not possible to blind participants in the intervention (24). Ideally, the included clusters (in this case, clinics/units) are randomised to when they will make the transition from control group to intervention group. However, considering that all staff at each participating unit/clinic will undergo a full-day training session, this requires a lot of planning on the part of the participating clinics. It has therefore not been possible to carry out randomisation, but instead the clinics have been slotted into the schedule in the stages that are best suited to the schedules of their own organisations.

[Insert Figure 1 around here]

Participants

Staff at six in-patient care units within internal medicine and geriatrics and three primary care centres in Sweden's south-east health care region (n=800) will be invited to participate in a full-day training session on elder abuse. All health care professionals participating in the training are eligible to participate in the study. Personnel who are not engaged in clinical work with older patients (age 65 and older) will be excluded.

Content of the educational intervention

The educational intervention consists of all staff participating in a full-day training session in which theory, group discussions and forum play are mixed. The theoretical pedagogical framework of the project is constructive alignment (26). In line with this, the training is based on participants' own previous experiences and focuses on the knowledge being transferred to the participants' day-to-day clinical practice. In order to create the right conditions for this, we discuss the participants' own experiences of encountering older victims and try to stimulate active participation via group discussions. The participants' own experiences are also used in the forum play, which also stimulates

embodied knowledge (27, 28). In order to facilitate transfer to clinical practice, we provide practical advice on questions that can be posed to older patients about abuse, and we present guidelines for what to consider when encountering older adults who have been subjected to different forms of abuse.

There is no evidence-based practice on how best to manage cases of elder abuse (29, 30). Even so, much can be done on an individual level. The recommendations given during the training day about how to manage cases of elder abuse are largely based on trauma-informed care (31, 32) and on providing information about the different sources of help available to victims in society and in health care.

Theoretical training (lectures and group discussions)

During the first part of the training day, we use lectures interspersed with video recorded meetings with abuse victims and group discussions. The first and last author are responsible for giving the lectures and leading the group discussions. During the lectures we focus on three themes: 1) What is elder abuse and what is my responsibility as a caregiver when encountering victims of elder abuse? 2) How can I ask questions about elder abuse? 3) An older patient told me about abuse – how do I handle the situation? For the second and third themes, we have produced short films that show encounters between health care providers and patients. One film is about asking questions about abuse and another is about handling the response. Two versions of each patient–provider encounter have been filmed in order to show how the different ways staff act affect the encounter with the patient. After viewing each film, the content is discussed in small groups: What went well in the encounter, what went less well and how could we do it differently? During the day, concrete guidance is also offered regarding how to ask questions, and we introduce the screening questionnaire REAGERA-S (33) as a tool to ask older adults about experiences of abuse. We also present local resources and guidelines relating to what staff could consider in terms of handling situations where they encounter victims of elder abuse.

Forum play

The second part of the training day is spent on forum play, a form of participatory theatre developed by Byréus (28), based on Boal's (27) forum theatre. The forum play is led by three drama teachers. Before starting, the participants form small groups to work out case descriptions of care situations pertaining to elder abuse that they themselves have perceived as challenging to deal with. In this way, participants' own experiences and real-world difficulties are used for the training and practical reasoning. Two pre-prepared patient cases based on research and clinical experience of difficulties during encounters with victims of elder abuse are also used. The forum play starts with the drama

teachers acting out the different situations, i.e., a staff–patient encounter where something went wrong or was difficult to manage. The situation is then acted out a second time, but this time the participants are invited to influence the encounter themselves. Participants are encouraged to say "stop" when the sequence of events is heading in the wrong direction. A participant then takes over the drama teacher's role and tries to act in a different way. Alternatively, the participant can give suggestions about how they would like the drama teacher to act differently. Thus, through the forum play, the participants and the drama teachers explore together how their way of acting can influence and improve the encounter with an older patient who has been subjected to abuse. This also reveals how there are alternative ways of acting, which may empower staff to deal with elder abuse. After each scene has been worked through, a brief comment is given concerning suggestions regarding ongoing management of the case, and how to provide help in this specific case. This provides participants with some model cases that they can later relate to when faced with similar situations.

Post-training reflection on changing practices

To further encourage the training being transferred to the participants' everyday practice, the training ends with a discussion on how to move forward. Can the training and the tools provided be incorporated into clinical routines?

Material and analysis

REAGERA-P is a validated questionnaire (34) that can be used to measure health care providers' preparedness to ask questions about abuse and manage the response. Figure 2 presents a schematic view of the factors measured in REAGERA-P.

[insert Figure 2 around here]

Retrospective selective review of medical records. For security reasons, the information about abusive experiences should be documented using specific templates in the medical records that are hidden in the online records. We will search these templates anonymously to investigate how frequent it is for the records at each participating clinic to document that a patient has been the victim of abuse. The validity of this data has not been established, and it will therefore be considered an experimental outcome. However, this could potentially represent an objective assessment of whether the intervention leads to increased identification of patients who have been subjected to elder abuse.

REAGERA-P will be distributed as an online survey immediately before and after the training day, and also on three more occasions, six months apart. In line with the stepped wedge trial design, participants who originally belong to the control group will later move to the intervention group.

Information from the medical records is retrieved for six-month periods over the course of the study. See Figure 1 for a schematic overview of times of data collection. All

Outcome measures

Main outcome: Changes in asking questions about abuse are measured as follows: 1) Changes in self-reported number of times the professional has asked patients questions about abuse (range 0–10 and above) as reported in REAGERA-P. The answers will be analysed both as a dichotomous variable (never/one or more times) and as a continuous variable. 2) Changes in the number of times data about abuse has been entered in the medical records on a clinical level.

Secondary outcomes: 1) Changes in the proportion of respondents reporting that victims of elder abuse were given adequate follow-up. 2) Changes in the proportion of respondents reporting suspicions about elder abuse but refraining from asking questions. 3) Changes in the proportion of respondents reporting a changed working practice at six months follow-up as a result of the education.

Secondary outcome and mediating variables: a) Self-efficacy for asking questions about abuse as well as handling the response. b) Sense of responsibility to ask questions. c) Individual-level perceived barriers to ask questions. d) Organisational-level perceived barriers to ask questions. e) Awareness of elder abuse and attitudes towards asking questions routinely.

Covariates potentially affecting both the intervention effectiveness and the outcome will be considered. These include background characteristics of participants on both individual and group levels, and are described in Figure 2.

Statistical analyses

Factors that will be considered in analyses are described in Figure 2. The potential effect of the intervention is expected to be mediated by one or more of the measures listed as secondary outcomes, as well as the covariates listed. Mixed models for repeated measures will be used to evaluate the outcomes. We will strive for parsimony; analysis will therefore be performed to determine which variables to include in multivariate analysis. Covariates that significantly affect the model will be included and cluster effects will be considered. Assumptions for models will be assessed graphically and, if needed, bootstrapping will be used to ensure model robustness. Subgroup analysis will be performed for each cluster (clinic), and also for type of clinic (internal medicine, geriatrics or primary health care) and profession. Missing data will be analysed and, if appropriate, multiple imputations will be considered.

Sample size calculation

Cluster sample size was calculated using the Shiny CRT Calculator web application (35). The significance level was set at 0.05 and power at 0.8. We planned for a three-step intervention and used the discrete time decay. Divergent cluster sizes were expected, and we used a coefficient of variation for a cluster size of 0.5. Proportion was set as an outcome, and we used data from a previous pilot study to estimate the proportion under control at 0.26 and the proportion under intervention at 0.56. A cluster size of 20 then sufficed to reach adequate power. Since our smallest expected cluster has 50 participants, even a response rate of less than 50% is adequate.

Patient and public involvement

Participant involvement is at the core of this study, as active involvement is encouraged throughout the training. A pilot study of the training was conducted in 2019–2020, and qualitative interviews were subsequently conducted with some participants to ensure that the training was relevant to their practice. This led to changes in the training that are implemented at this stage, e.g., a stronger focus on how to handle cases and providing information about local societal resources available to victims. Cognitive interviews with health care providers were also used as one of the measures to validate the questionnaire used to evaluate the intervention (REAGERA-P) (34). This was done to ensure the comprehensibility of the questions, and also to make sure that the questions are perceived as relevant.

Ethics and dissemination

The study has been approved by the Swedish Ethical Review Authority (reference no. 2020-02548). Participants will be asked for their informed consent to participate every time they fill out the web survey. The database will be securely stored by Region Östergötland and only authorised persons will have access to the data. The results of the study will be published in peer-reviewed journals and conference proceedings. Anonymous data will be made available by the primary investigator upon reasonable request. As a final product of the study, a manual/clear description of the course content will be published. The purpose is to use this manual/description to disseminate the course to other clinics or organisations that wish to use it.

Contributorship statement

The last author (JS) wrote the first draft of the study protocol. All authors have contributed to developing the educational model and planning the study. All authors also performed critical revisions for important intellectual content, and read and approved the final manuscript.

Conflicts of interests

The authors have no competing interest to declare.

Competing interests

The authors have no competing interest to declare.

Funding

This study will be funded by internal sources at Region Östergötland (no specific award/grant). In addition, there are pending applications for external funding. However, no specific grants from any funding agency in the public, commercial or not-for-profit sectors have been granted so far. Funder will not have any role in study design, data collection, management, analysis, interpretation of data, writing report or decision to submit the report.

Data sharing statement

There is no data supporting this study protocol. When the data collections has been completed, anonymous data will be made available by the primary investigator upon reasonable request.

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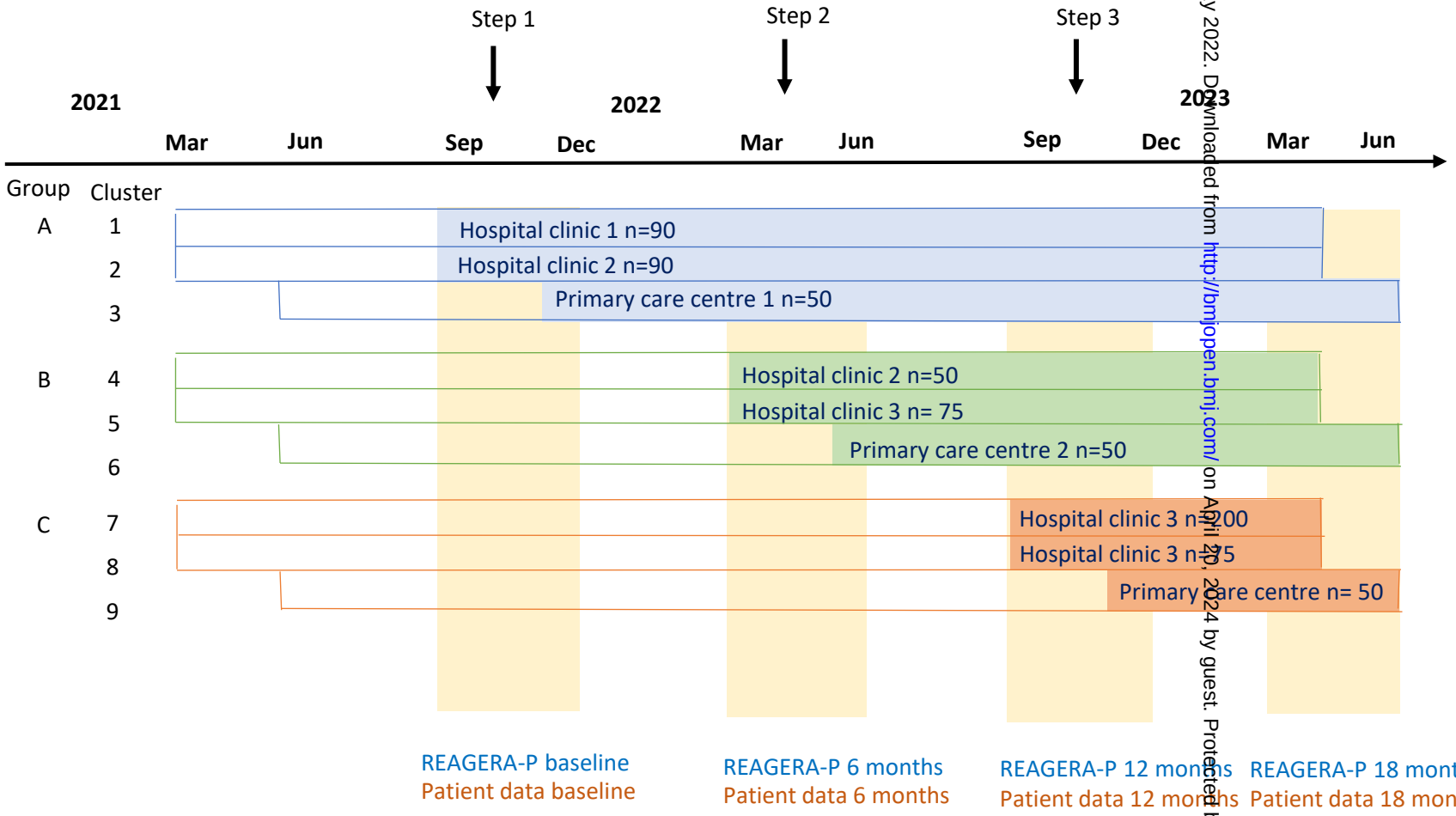
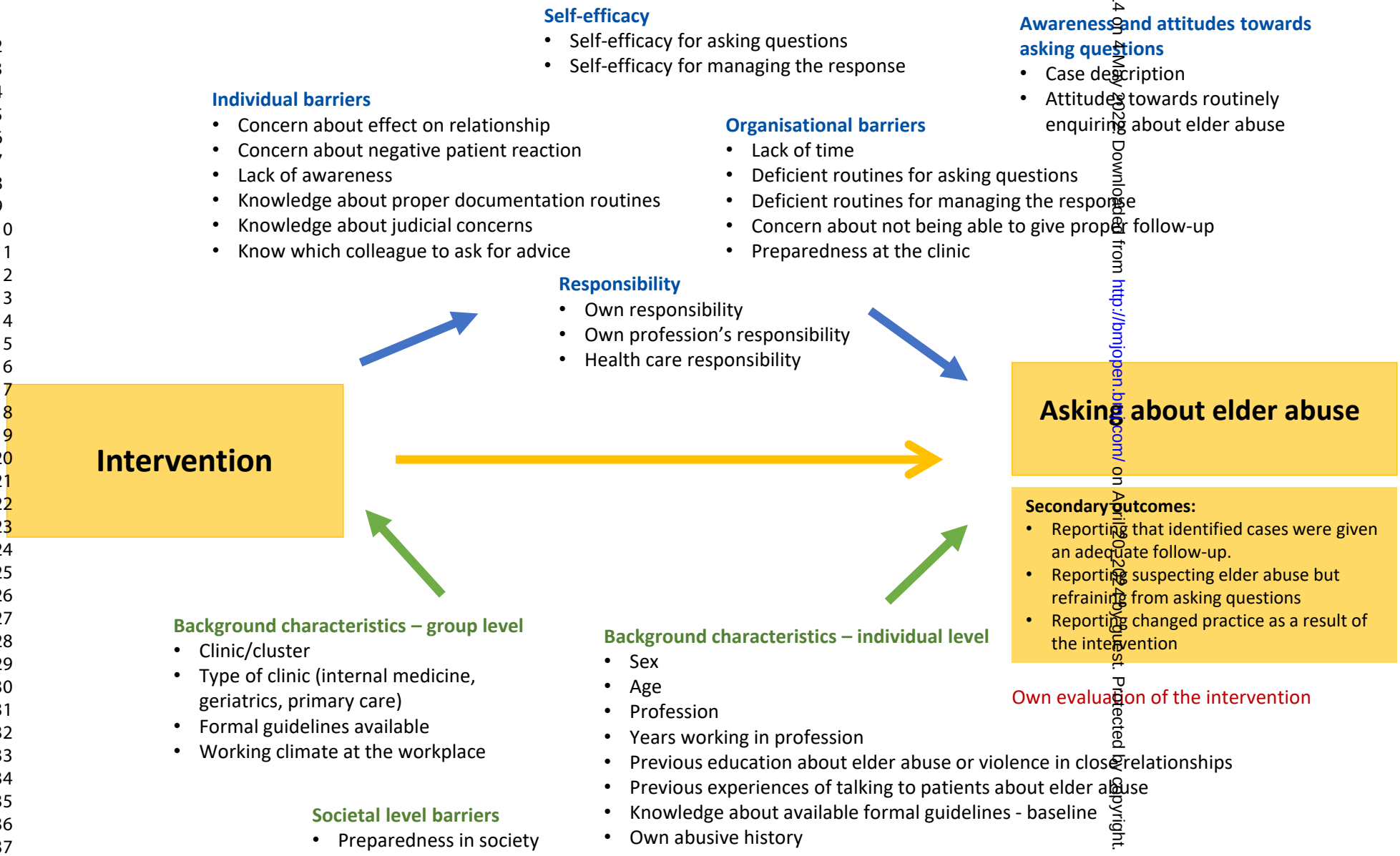
Figure legends

Figure 1. An illustration of the non-randomised stepped wedge trial design and times of data collection. The empty part of the bar is time before the educational intervention (control). The coloured bar is time after exposure (intervention). Data is collected at four points in time (illustrated by the yellow vertical areas), and the first data collection relates to experiences during the six months prior to trial start.

Figure 2. Variables included in study and expected associations. Blue labelled variables are secondary outcomes as well as factors expected to mediate the effect of the intervention. Green labelled variables are covariates.





SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	10
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	10
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	10
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-4
	6b	Explanation for choice of comparators	3-4

Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5-7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1 and page 7
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation:			

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 7 and fig 2
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	8
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	8
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	8

	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	8
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	9
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	7,9
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	9-10

Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	9
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	9
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	9
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

The Responding to Elder Abuse in GERiAtric care (REAGERA) educational intervention for health care providers. A non-randomised stepped wedge trial.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-060314.R1
Article Type:	Protocol
Date Submitted by the Author:	05-Apr-2022
Complete List of Authors:	Ludvigsson, Mikael; Linköping University, Department of Psychiatry, and Department of Biomedical and Clinical Sciences; Linköping University, Department of Acute Internal Medicine and Geriatrics, and Department of Health, Medicine and Caring Sciences Motamedi, Atbin; Linköping University, Department of Emergency Medicine in Norrköping, and Department of Health, Medicine and Caring Sciences Westerlind, Björn; County Hospital Ryhov, Department of Geriatrics, Region Jönköping County; Linköping University, Department of Health, Medicine and Caring Sciences Swahnberg, Katarina; Linnaeus University, Department of Health and Caring Sciences Simmons, Johanna; Linköping University, Department of Acute Internal Medicine and Geriatrics, and Department of Health, Medicine and Caring Sciences
Primary Subject Heading:	Medical education and training
Secondary Subject Heading:	Public health, Geriatric medicine, General practice / Family practice, Nursing, Patient-centred medicine
Keywords:	EDUCATION & TRAINING (see Medical Education & Training), GERIATRIC MEDICINE, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, MEDICAL EDUCATION & TRAINING

The Responding to Elder Abuse in GERiAtric care (REAGERA) educational intervention for health care providers. A non-randomised stepped wedge trial.

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Key Words

Elder abuse, Medical education, Forum Play, Forum Theatre

Word count: 4564

Abstract

Introduction

Elder abuse is prevalent and associated with different forms of ill health. Despite this, health care providers are often unaware of abusive experiences among older patients and many lack training about elder abuse. Th overall aim of this study is to determine the effectiveness of an educational intervention on health care providers' propensity to ask older patients questions about abusive experiences.

Methods and analysis

Health care providers at hospital clinics and primary health care centres in Sweden will undergo a full day education about elder abuse between the fall of 2021 and spring of 2023. The education consists of 1) Theory and group discussions; 2) Forum theatre, a form of interactive theatre in which participants are given the opportunity to practise how to manage difficult patient encounters; 3) Post-training reflection on changing practices.

The design is a non-randomised cluster stepped wedge trial in which all participants (n=750) gradually transit from control group to intervention group with six months interval, starting fall 2021. Data is collected using the REAGERA-P questionnaire which was distributed to all clusters at baseline. All participants will also be asked to answer the questionnaire in conjunction with participating in the education as well as at 6 and 12 months follow up. Main outcome is changes in self-reported propensity to ask older patients questions about abuse post-intervention compared to pre-intervention. Linear mixed models including cluster as a random effect will be used to statistically evaluate the outcome.

Ethics and dissemination

The study has been approved by the Swedish Ethical Review Authority. The results will be published in peer-reviewed journals and conference proceedings. If the intervention is successful, a manual of the course content will be published so that the education can be disseminated to other clinics.

Registration

This trial is registered at clinicaltrials.gov (ID no. NCT05065281).

Strengths and limitations of this study

- This study includes a large cohort (n=750) of health care providers who will undergo education about how to detect and respond to elder abuse.

- The education tested is brief (one day), yet comprehensive, combining theory and group discussions about elder abuse with interactive practical skills training, i.e. forum theatre.
- The education tested will be included in the ordinary continued educational programs at the clinics participating in the study and all members of staff are anticipated to participate, providing a sample that is generalizable to health care providers in geriatrics, internal medicine, and primary care.
- One limitation of the study is that some important stakeholders are not included, e.g. health care providers in surgical specialities and emergency medicine.
- The stepped wedge design provides an opportunity to assess if factors on the cluster level, i.e. clinical level, impact the results.

Introduction

Past year prevalence of elder abuse in community samples is reported to be around 10-15% worldwide (1, 2). Studies conducted among the most vulnerable older adults, e.g., those residing in nursing homes or suffering from cognitive impairment, often report much higher prevalence rates, around 30-60% (2, 3). In this study, we use the WHO definition of elder abuse, including physical, psychological, sexual and economical abuse, as well as neglect occurring in any relationship where there is an expectation of trust, e.g., relatives as well as health and social care staff (4).

Elder abuse is associated with mental ill health, physical disability, an increased number of hospitalisations and an increased need for assisted living (2, 5-7). Though many older adults who are exposed to abuse report that they need more help than they are currently receiving, they are also often found to be reluctant to seek help (8, 9). Known barriers for help-seeking includes shame and not knowing where to turn for help (10, 11). Therefore, the health care system is important for identifying victims of elder abuse (7, 12), but many patients are never asked questions about abuse by health care professionals (13). Also, health care providers are often reported to be insufficiently prepared to detect and manage cases of elder abuse (7, 14). Barriers towards identifying victims have been reported on a personal level among care givers, e.g., providers feeling unsure about what constitutes abuse, unsure about what their responsibility is or feeling uneasy about addressing the issue. Barriers at the organizational level are also prominent, e.g., time restraints, lack of guidelines and concerns that support system may not be able to suffice the need of victims (9, 15-19).

Another barrier for detecting abuse is the difficulties that lies in identifying symptoms of abuse. This difficulty particularly applies to older adults whose medical conditions may mask signs of abuse, e.g., an increased tendency to bruise and an increased risk of falling as well as sustaining injuries after a fall. Thus, there is an obvious risk of caregivers not interpreting injuries as a sign of abuse, but also of suspecting that the patient's injuries are due to abuse even when they are not (9, 20). In addition, physical signs of abuse are often absent, and staff need to be attentive to other signs, e.g., psychological symptoms or social problems. However, such symptoms might also be absent or difficult to detect. Considering the complexity of the issue, staff needs education about elder abuse but in Sweden, as in many other countries, a large proportion of health care providers have never received any training about elder abuse (19).

This study protocol describes the evaluation of an educational model aiming at increasing participants' propensity to ask older patients questions about abuse, by helping participants to overcome personal and organizational barriers for doing so. The specific learning objective of the education is therefore to A) increase providers' awareness about elder abuse and sense of

responsibility to care for victims; B) increase providers' perceived ability to ask questions about abuse; C) increase providers perceived preparedness to manage cases of elder abuse; D) increase organizational preparedness to care for older adults subjected to abuse.

The pedagogical framework underling the educational model is inspired by constructive alignment theory, stating that learning objectives, learning activities and evaluation should be clearly aligned. (21). Since the education is directed at professionals rather than students, no examination of the acquired competence will be conducted, instead the evaluation constitutes the outcome measures chosen to measure effectiveness of the model. As illustrated in figure 1, learning activities, i.e. a mix of theoretical lectures, group discussions and forum theatre, were chosen to match the previously stated learning objectives. Forum theatre is used as practical skills training and is a form of interactive theatre where participants – together with drama pedagogues – practise dealing with difficult situations and finding alternative ways of acting. Using interactive learning activities, including practical training with simulated patients have previously been recommended when educating about elder abuse (22-24). The forum theatre is expected to increase participants confidence in managing difficult situations which in turn is expected to have a facilitating effect on asking questions about abuse in future encounters. In both group discussions and forum theatre, participants are encouraged to exchange ideas and share previous experiences, to make the education relevant for their everyday practice. This is in line with constructive alignment theory, which stipulate that learners actively construct their own knowledge based on e.g., previous experiences, motives, assumptions and intentions (21). Also, to facilitate transferral of acquired knowledge to practice we will give examples on how to formulate questions about abuse and provide contact information to local support organizations. Previously, it has been highlighted that training should be adapted to local conditions so that the education can easily be translated into everyday practice (25). A pilot study evaluating the proposed educational model has been carried out previously and the results of that study will be published separately (26).

[Insert figure 1 around here]

Aim

The overall aim of the project is to determine the effectiveness of an educational intervention on health care providers' propensity to ask older patients questions about abusive experiences. More specifically, we will:

1) Investigate whether the education increases propensity to ask questions about abuse.
2) Investigate whether the education affects participants' perceived barriers to asking questions, i.e. a) awareness and sense of responsibility to care for victims of abuse b)

perceived ability to ask questions about abuse c) perceived preparedness to manage cases of elder abuse and d) perceived preparedness at the clinic to care for older adults subjected to abuse.

Method and analysis

Design

The design is a non-randomised stepped wedge trial, a type of controlled cluster cohort study in which the participants gradually move from control group to intervention group (27, 28). In this study, a cluster entail a whole clinic or a unit at a clinic and at the end of the study all clusters will have completed the intervention, i.e., participated in the education. Data will be collected for all participants both pre- and post-intervention. See Figure 2 for a schematic overview of the study design and times points for data collection. The stepped wedge design is recommended when, for practical and logistic reasons, it is difficult to implement an intervention for all participants simultaneously. A strength of the cluster design is that it allows all health care providers at the respective cluster to participate in the education together. This is likely to increase the collective preparedness to care for victims of elder abuse at each workplace, while simultaneously keeping the risk of contamination between different clusters at a minimum.

[Insert Figure 2 around here]

The intervention will be rolled out during four periods between September 2021 and spring 2023 (figure 2). A complete stepped wedge design would therefore entail at least five measurement points, which was deemed to be a too heavy response burden. Therefore, an incomplete design was chosen, i.e., six periods are used, but every cluster is only included at four measurement points: at baseline, in conjunction with the education, at six months follow up and at twelve months follow up. The times of data collection is illustrated in figure 1. Similar incomplete designs have been described previously (28, 29). For practical reasons the primary care centres included in the first study period had to be included later than the hospital clinics, i.e., in December 2021. To avoid a data collection period during the summer vacation, their first follow up will be in late august, i.e., eight months post intervention. Thereafter they will fall into the same pattern of data collection at six months interval as the other clinics. The six month interval was chosen because it provides an intermediate (six months) and long-term (twelve months) follow up that allows for a reasonable evaluation of the effect of the education. Ideally in a stepped wedge trial, the included clusters are randomised to when they will make the transition from control group to intervention group. However, considering

that all staff at each participating clinic or unit will undergo a full-day training session, this requires a lot of planning on the part of the participating clinics. It was therefore not possible to carry out randomisation, but instead the clinics were slotted into the schedule in the stages that were best suited to the schedules of their own organisations.

Participants

Staff at six in-patient care units within internal medicine and geriatrics at four of the six hospitals in two regions (Region Östergötland and Region Jönköpings Län) in Sweden, as well as three of the 45 primary care centres in Region Östergötland will be invited to participate in a full-day education concerning elder abuse. The education is included in the clinics continuing education program and as far as possible (considering clinical responsibilities) all staff, e.g., nurses, assistant nurses, physicians, occupational and physical therapists, will be scheduled to take part in the education. All staff participating will be asked for inclusion in the study but agreeing is not a prerequisite to partake in the education. Staff who are not engaged in clinical work with older patients (age 65 and older) will be excluded from the study but welcome to participate in the education. Approximately 750 health care providers will be asked to participate. The number is estimated based on the known number of participants in the educations during the first period of data collection (fall 2021) and the anticipated number of participants in the forthcoming educations, as provided by management at the participating clinics (figure 2).

The sample of units was based on convenience, i.e. the clinics were recruited with the help of personal connections members of the research team had. The researchers are however not generally known to the health care providers participating in the study, with two notable exceptions: 1) Two of the researchers (JS and ML) – who are also responsible for delivering the education – are employed at the clinic that first underwent the education; 2) One other researcher (BW) is employed at one of the other geriatric clinics included. He does however not have an active role in delivering the education.

Learning activities – Content of the educational intervention

The different learning activities used during the education and their alignment with the learning objectives and evaluation is illustrated in figure 1.

Theoretical training (lectures and group discussions)

During the first part of the educational day, two members of the research group (JS and ML) give lectures interspersed with group discussions. Three themes are covered:

1) **What is elder abuse**? The education starts by showing a short film portraying a woman subjected to abuse by her partner. The film is shown to illustrate the complexity of elder abuse and to elicit

emotions. In the associated lecture the definition of elder abuse, prevalence, risk factors and health consequences of elder abuse are presented. Group discussions focus on what constitutes elder abuse as well as participants' own experiences of meeting patients subjected to abuse.

2) **How can I ask questions about abuse?** We present regulations from the Swedish National Board of Health and Welfare stating that health care providers should ask questions about abuse whenever there are signs or symptoms that may indicate abuse (30). Symptoms that may be associated with abuse are discussed but we emphasise that there are no pathognomonic signs and that questions often need to be asked regardless of indicators of abuse. The self-administered questionnaire REAGERA-S (31) is introduced as a tool for asking older adults about experiences of abuse. Associated group discussions focus on how to ask questions about abuse, and we allow some time to practice using the REAGERA-S.

3) **An older patient told me about abuse – how do I handle the situation?** There is no evidence-based practice on how to best manage cases of elder abuse (32, 33). Instead, interventions against elder abuse must be individually tailored to match the unique needs and preferences of the older adult (34). We introduce trauma-informed care as a concept, meaning e.g., being aware of trauma symptoms, working to prevent re-traumatization in health care and emphasising survivors' voice and empowerment in the care provided (35, 36). We also present local resources for victims and regional guidelines about managing cases of elder abuse. Group discussions focuses on how to handle the situation when an older patient discloses abusive experiences.

Short films that show patient-provider encounters are used to introduce group discussions during theme two and three. Two versions of each patient–provider encounter have been filmed to show that the encounter develops differently depending on how staff act. One pair of films are about asking questions about abuse (theme 2) and one set of films are about responding when a patient discloses abusive experiences (theme 3). After viewing each film, the content is discussed in small groups: What went well in the encounter, what went less well and how can it been done differently?

Forum theatre

The second part of the educational day is devoted to forum theatre, a form of interactive theatre (37) led by three drama pedagogues. Before starting, the participants form small groups to work out case descriptions of care situations pertaining to elder abuse that they themselves have perceived as challenging to deal with. Two pre-prepared and rehearsed patient cases based on research and clinical experience of difficult encounters with victims of elder abuse are also used. The forum theatre starts with the drama pedagogues acting out a provider–patient encounter where something went wrong or was difficult to manage. The scene is then acted out a second time, but this time the

participants are invited to intervene in the encounter by saying "stop" when the sequence of events is heading in a dysfunctional direction. The participant saying stop then takes over the role of the drama pedagogue acting as the health care provider and tries another way of managing the situation played out in the scene. Alternatively, the participant instructs the drama pedagogue how to act differently. Thus the participants and the drama pedagogues together explore how their ways of acting can influence and improve a difficult encounter. While working with the scene, participants and drama pedagogues also engage in discussions about what is happening, the difficulties encountered and potential solutions. After each scene has been worked through, a brief remark is given by JS or ML regarding how to provide help in the specific case. This provides participants with some model cases that they can later relate to when faced with similar situations. Previously, forum theatre has been described as an innovative training model that stimulates reflection and learning within the health care system (38).

Post-training reflection on changing practices

To facilitate transferral of the newly gained knowledge to participants' everyday practice, the educational day ends with a discussion on how to move forward. How can the training and the tools provided during the education be incorporated into clinical routines? This is first discussed in small groups and then further elaborated on with all participants, with the intention to stimulate thoughts and plans about how preparedness to care for victims can be improved at the clinic.

Material and analysis

Data will be collected with the REAGERA-P (Responding to Elder Abuse in GERiAtric care – Provider questionnaire). It is a validated instrument (39) that can be used to measure health care providers' preparedness to ask older patients questions about abuse and manage the response. The items of relevance for this study are presented in table 1 and the complete REAGERA-P as supplementary file 1.

[insert Table 1 around here]

Construct and convergent validity of the REAGERA-P was previously tested in a sample of 154 health care providers by using factor analysis, test of internal consistency and by investigating associations between relevant variables (39). Based on lessons learned in that data collection the instrument was further improved and has later been used to evaluate a pilot study of the current educational intervention (26). In the pilot study, a possible ceiling effect was found for two items about sense of responsibility and therefore the response categories were modified for the current study, i.e., changed from a four-point ordinal scale to a six-point ordinal scale. Also, to better capture change in frequency of asking questions about abuse, response categories for the main outcome measure

about self-reported propensity to ask questions was changed from a four-point ordinal scale (Never, once, 2-4 times, 5 times or more) to an 11-point scale (0-10 or more).

The concepts used to evaluate the respective learning objectives is described in figure 1 and the corresponding items in REAGERA-P can be found in Table 1. REAGERA-P will be distributed as an online survey and all items are measured at each data collection point, except the case vignette. Because we anticipate a learning effect if using the case vignette to many times it will only be included at baseline (autumn 2021) and at the measurement one year later (autumn 2022). Consequently, for some clusters it will be measured twice pre-intervention but for others it will be measured at the 6-months or 12-months follow up. Also, the data collection point that occurs in conjunction with the education consists of a full data collection as the first part of the educational day and a limited data collection at the end of the day. The latter includes the items about cause for concern when asking questions about abuse, sense of responsibility, and self-efficacy for asking questions and managing the response, as well as some items used to evaluate the intervention.

Since we use an online survey, data input is conducted during the time of data collection. No interim analysis or other monitoring of data will be conducted during the time of data collection.

Retrospective selective review of medical records. For security reasons, it is recommended in Sweden that the information about abusive experiences should be documented using specific templates in the medical records that are hidden in the online records. We will retrieve anonymous statistics about how often these templates are used on a clinic level, i.e., how many patients at each clinic that are identified as victims of abuse during the study period. The validity of this data has not been established, and it will therefore be considered an experimental outcome. However, this could potentially represent an objective assessment of whether the intervention leads to increased identification of patients subjected to elder abuse.

Statistical analyses

The background characteristics of participants will be explored using descriptive statistics and comparisons will be made between clusters to detect significant differences. Missing data will be analysed and, if appropriate, multiple imputations will be considered. Attrition analysis will be conducted using e.g. chi square test and student's t-test to detect differences between those lost to follow up and those retained.

In a stepped wedge trial, results are compared across unexposed and exposed observation periods in the clusters, similar to the control and intervention arm in a parallel cluster trial (40). The primary effect of this study will hence be calculated by comparing the main outcome (propensity to ask

questions about abuse) in all clusters pre-intervention with all clusters post-intervention. Both mean difference in reported frequency of asking questions and changes in proportion of participants that report ever having asked questions about abuse will be reported. For the continuous outcome a linear mixed effect model will be used and for the binary outcome a generalised linear mixed effect model. The models will consider repeated measures and include cluster as random effect to determine if the anticipated effect of the model is dependent on the cluster, i.e. unit or clinic. During a stepped wedge trial more and more clusters will gradually transition from unexposed to exposed status, meaning that observation in the exposed status will on average be of a later date than the unexposed observation (40). This may introduce a bias in the study considering that there may be underlying temporal trends affecting the outcome, e.g. an increasing awareness of elder abuse in society over time. Therefore, both intervention status and time will be included as fixed effects in the models. Also, models will be adjusted for covariates, e.g. background characteristics, significantly associated with the outcome.

As previously described, we propose that the education will work by participants overcoming personal and organizational barriers towards asking older patients questions about abuse. The items in REAGERA-P used to evaluate the effect on the different barriers and facilitators are described in figure 1 and they will be included in linear models (for continuous outcome) and generalised linear models (for binary outcomes) to determine the effect of the intervention on these outcomes. If results support the theoretical model, efforts will be made to test if changes in perceived barriers mediate a potential effect of the intervention on the primary outcome, i.e. asking questions about abuse.

Data from the medical records will be retrieved for the following periods a) 6 months pre-intervention, b) 0-6 months post intervention and c) 6-12 months post intervention. A linear mixed effect model will be used to investigate changes concerning how many victims are identified pre- and post-intervention at the participating clinics.

In all models, we will strive for parsimony; analysis will therefore be performed to determine which variables to include in multivariate analysis and only covariates that significantly affect the model will be included. Assumptions for models will be assessed graphically and, if needed, bootstrapping will be used to ensure model robustness. Significance level will be set at p=0.05 and results will be reported with 95% confidence intervals.

Sample size calculation

Cluster sample size was calculated using the Shiny CRT Calculator web application found at https://clusterrcts.shinyapps.io/rshinyapp/. A detailed description of the underlying rational for the

calculations conducted by the web application is presented elsewhere (41), as well as on the website. The significance level was set at 0.05 and power at 0.8. Initially we had planned a complete four period stepped wedge design and hence, that was used in the sample size calculation together with the discrete time decay. Divergent cluster sizes were expected and coefficient of variation for a cluster size was set at 0.5. Results from the pilot study was used to estimate cluster auto correlation at 0.6. Proportion was set as outcome, and we used data from the pilot study to estimate the proportion under control at 0.26 and the proportion under intervention at 0.56. An illustration of the trade-off between cluster size and number of clusters per arm calculated can be found in as supplementary file 2. The illustration also includes the parameters used in calculation and show that a cluster size of 10 sufficed to reach adequate power. Since our smallest expected cluster has 31 participants, even a response rate of less than 40% is sufficient.

Patient and public involvement

A pilot study of the education was conducted in 2020, and qualitative interviews were subsequently conducted with some participants to ensure that the education was relevant to their practice (26). This led to changes in the education that are implemented at this stage, e.g., a stronger focus on how to manage cases and providing information about local societal resources available to victims. Cognitive interviews with health care providers were also used as one of the measures to validate the questionnaire used to evaluate the intervention (REAGERA-P) (39). This was done to ensure the comprehensibility of the questions, and also to make sure that the questions used for evaluation are perceived as relevant. There was no patient involvement when constructing the intervention. However, the research group has previously conducted qualitative studies with older patients subjected to abuse (34) and the results of those interviews have inspired the content of the intervention.

Ethics and dissemination

The study has been approved by the Swedish Ethical Review Authority (reference no. 2020-02548). Informed consent (Supplementary file 3) is obtained as the first part of REAGERA-P and must be given before starting to fill out the questionnaire at all data collection points. The database will be securely stored by Region Östergötland and only authorised persons will have access to the data. The results of the study will be published in peer-reviewed journals and conference proceedings. Anonymous data will be made available by the primary investigator upon reasonable request after results have been published. As a final product of the study, a manual of the course content will be published. The purpose is to use this manual to disseminate the course to other clinics or organisations that wish to use it.

Discussion

This study protocol describes the evaluation of an educational intervention about elder abuse, directed at health care providers. One strength of the educational model tested is combining theory with interactive components, i.e., group discussions and forum theatre. Interactive learning activities have previously been recommended when educating about elder abuse (22-24).

Two of the researchers (JS and ML) are responsible for giving the lectures and moderating group discussions during the education. They are employed at one of the clinics that underwent the education in September 2021. It is possible that this circumstance will affect the outcome of the intervention, e.g. knowing the researchers might influence the experience of the education and potentially also participants' assessments in the REAGERA-P. However, since the researchers are not generally known at the other participating clinics such a potential effect is expected to have a limited impact on the overall results and it is adjusted for by including cluster effect in the analysis.

By including a measurement point at the start of the educational day, most staff participating in the education are expected to also be included in the study. In fact, preliminary analysis reveals that around 99% of those participating in the education during the fall of 2021 choose to participate in the study. However, we anticipate that it will be a challenge to retain participants over multiple data collection points. One of the reasons for choosing a stepped wedge trial was that all participants will be offered the intervention, which is expected to increase motivation to participate in follow up measurements. Hence participants lost to follow up will be fewer than if a parallel controlled cluster design would have been chosen. Efforts have also been made to assure motivation among the leadership of each clinic for participation in the study and allowing the education to be a part of the continuing educational program at the clinics. By including all staff, collective learning is stimulated which likely creates an increased preparedness to care for victims on both the individual and clinical level. It is also a strength of the study design that all staff at the clinics are invited to participate because it increases generalizability of the results. However, only geriatric, internal medicine and primary care clinics are included in the study and the results may hence not be generalized to staff at other clinics.

The objective of the educational model evaluated is that health care providers should start asking older patients questions about abuse more frequently than before. If successful, a manual of the course content will be published, which may facilitate future education of health care providers concerning elder abuse and inspire other similar programs and studies. By extension more victims of elder abuse will hopefully be identified in health care. This is an important, but only a small piece of a more comprehensive puzzle to improve societal response to elder abuse. Much more research is

needed considering how effective response systems can be constructed and how elder abuse can be prevented (32, 35, 42, 43).

Contributorship statement

The study concept was conceived by JS who is also the primary investigator. JS, ML, KS and AM planned the content of the educational intervention. JS, ML, KS and BW planned the study design and data collection. JS is responsible for data collection and AM will conduct data analysis assisted by JS, ML, KS and a statistican. JS wrote the first draft of the manuscript and ML, KS, BW and AM performed critical revisions for important intellectual content. JS, ML, BW, KS, AM all read and approved the final manuscript.

Conflicts of interests

The authors have no competing interests to declare.

Funding

This study is mainly funded by internal sources at Region Östergötland (no specific award/grant). Also, funding has been granted by the Kamprad family foundation (grant no 20210151). Funders have had no role in study design and will not have any role in data collection, management, analysis, interpretation of data, writing report or decision to submit the reports.

Data sharing statement

There is no data supporting this study protocol. When the data collection has been completed and reports are published, anonymous data will be made available by the primary investigator (JS) upon reasonable request.

Acknowledgement

The authors wish to acknowledge Karolin Olstam for her important help in producing the short films used to introduce the group discussion under theme two and three in the theoretical part of the education.

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Figure legends

Figure 1. Theoretical model. An illustration of the alignment between learning activities (yellow), learning objective, i.e., barriers and facilitators on a personal (green) and organizational (blue) level as well as evaluation (red).

Figure 2. Design of the study and data collection points. An incomplete stepped wedge trial is planned. All clusters are measured pre-intervention (yellow squares = baseline and in conjunction with the educational day) and post-intervention (blue squares = at 6-8 months and 12-14 months follow up). Time of intervention is denoted by the red contour.

Table 1. Items in REAGERA-P used to evaluate the intervention

Barrier / Faciliator	Item used to evaluate	Response categories
Main outcome		
Propensity to ask questions	- How many times have you asked older patients questions about abuse in the past six months?	Ordinal 0-10 or more, Do not remember
Awareness of elder abuse and sense of responsibility to care for victims		
Lack of awareness	- To what extent do you think that the following factors prevent you at your workplace from asking older patients questions about abuse? • Insufficient awareness of the problem	• Not at all • To a small extent • To a rather small extent • To a rather large extent • To a large extent • To a very large extent
Responsibility	- How much responsibility do you think that a) the health care services, b) you, in your professional role have for identifying older patients who currently are, or have previously been, subjected to abuse? - Participants are also asked to rate how much responsibility different health care professionals have for asking questions about abuse.	• None • Little • Fairly little • Quite a lot • A lot • Very much
Case vignette	A case vignette was used to measure awareness of elder abuse and tendency to ask older patients questions about abuse. More and more indicators and symptoms of abuse are added in subsequent steps of the case vignette and respondents are asked repeatedly how likely it is, considering what is known at each point, that they would ask the patient questions about abuse. Reporting asking questions early on in the vignette is interpreted as high awareness and a high propensity for asking questions.	• Not at all likely • Not particularly likely • Somewhat likely • Very likely
Perceived ability to ask questions about abuse		
Self-efficacy for asking questions about abuse	- At present, how would you manage to do the following things in your work? A sum-scale consisting of three items, e.g., asking question about abuse to an older patient who has no clear indications of now being or having previously been, subjected to abuse. (Cronbach's alpha in validation study=0.75.)	• Ordinal scale from 0 =would manage it very poorly to 10=would manage it very well
Cause for concern	-How concerned are you about the following things when it comes to asking older patients questions about abuse? • That the patient reacts negatively if I ask questions • That the patient-care provider relationship will be negatively impacted if I ask questions	• Not at all concerned • A little concerned • Somewhat concerned • Very concerned

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Preparedness to manage cases of elder abuse		
Self-efficacy for managing the response	- At present, how would you manage to do the following things in your work? A sum-scale consisting of five items, e.g., helping an older patient subjected to abuse to make a report to the police or social services. (Cronbach's alpha in validation study =0.87.)	• Ordinal scale from 0 =would manage it very poorly to 10=would manage it very well
Cause for concern	- How concerned are you about the following things when it comes to asking older patients questions about abuse? • That I will not be able to offer the patient a good follow-up	• Not at all concerned • A little concerned • Somewhat concerned • Very concerned
Collegial support	- If you would like help to handle the situation when an older patient tells you about abuse, do you know who at your workplace you could turn to?	• Yes • No
Knowledge about proper documentation routines	- Do you know what you should do to document what patients tell you about abuse in a correct and secure way in the medical record?	• Absolutely • To a large extent • To some extent • Not really
Knowledge about judicial concerns	- Do you think you have enough legal knowledge, for example about when and to whom one can/must report if an older patient is mistreated and what secrecy rules apply?	• Absolutely • To a large extent • To some extent • Not really
Preparedness at the clinic to care for victims of elder abuse		
Deficient routines	- To what extent do you think that the following factors prevent you at your workplace from asking older patients questions about abuse? • Deficient routines at the workplace for asking questions • Deficient routines at the workplace for handling the answer.	• Not at all • To a small extent • To a rather small extent • To a rather large extent • To a large extent • To a very large extent
Preparedness at clinic and in society	- How do you think the preparedness at a) your workplace b) in society is for taking care of older patients subjected to abuse?	• Very good • Fairly good • Somewhat inadequate • Very inadequate • Don't know what preparedness there is

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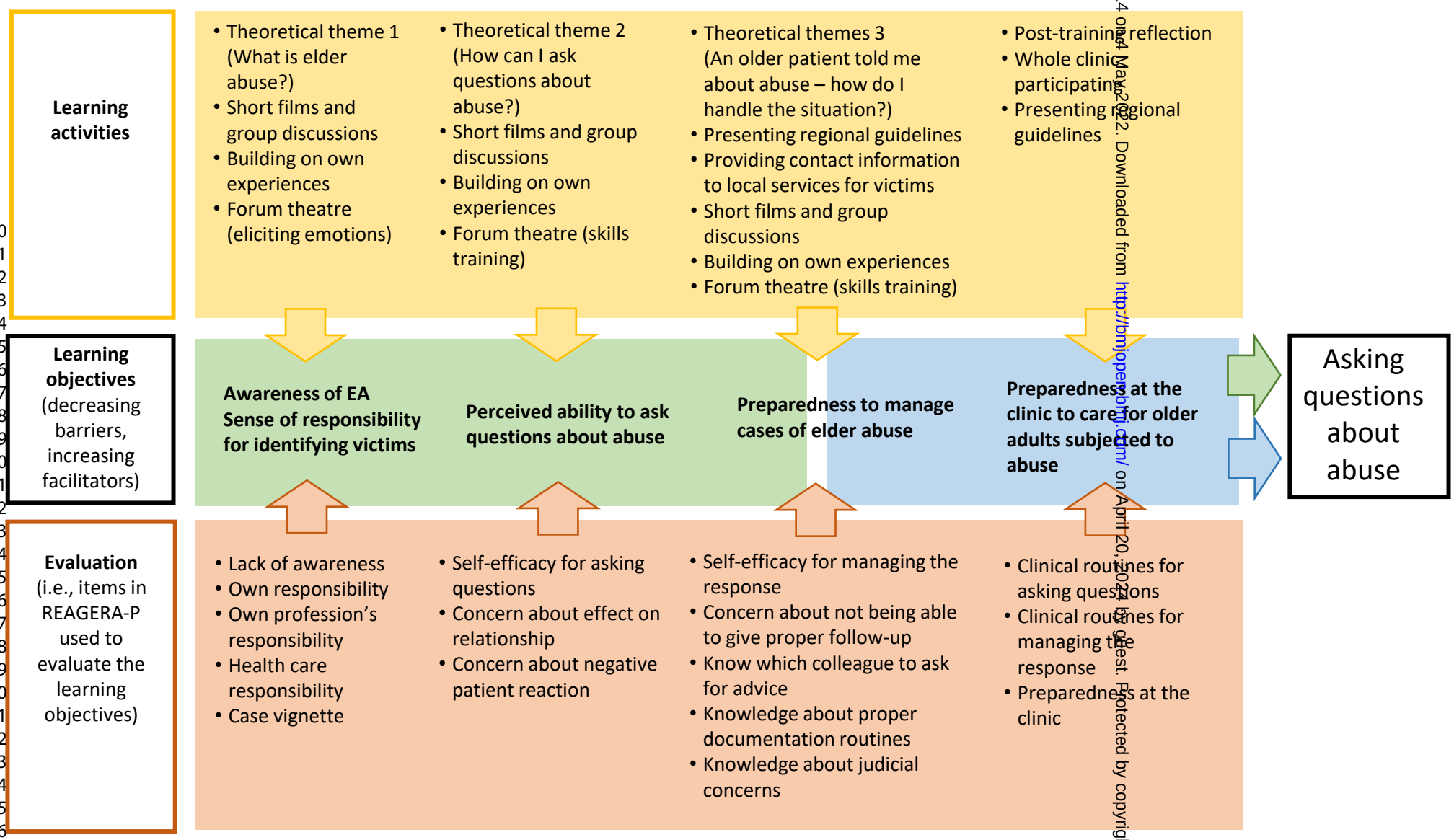
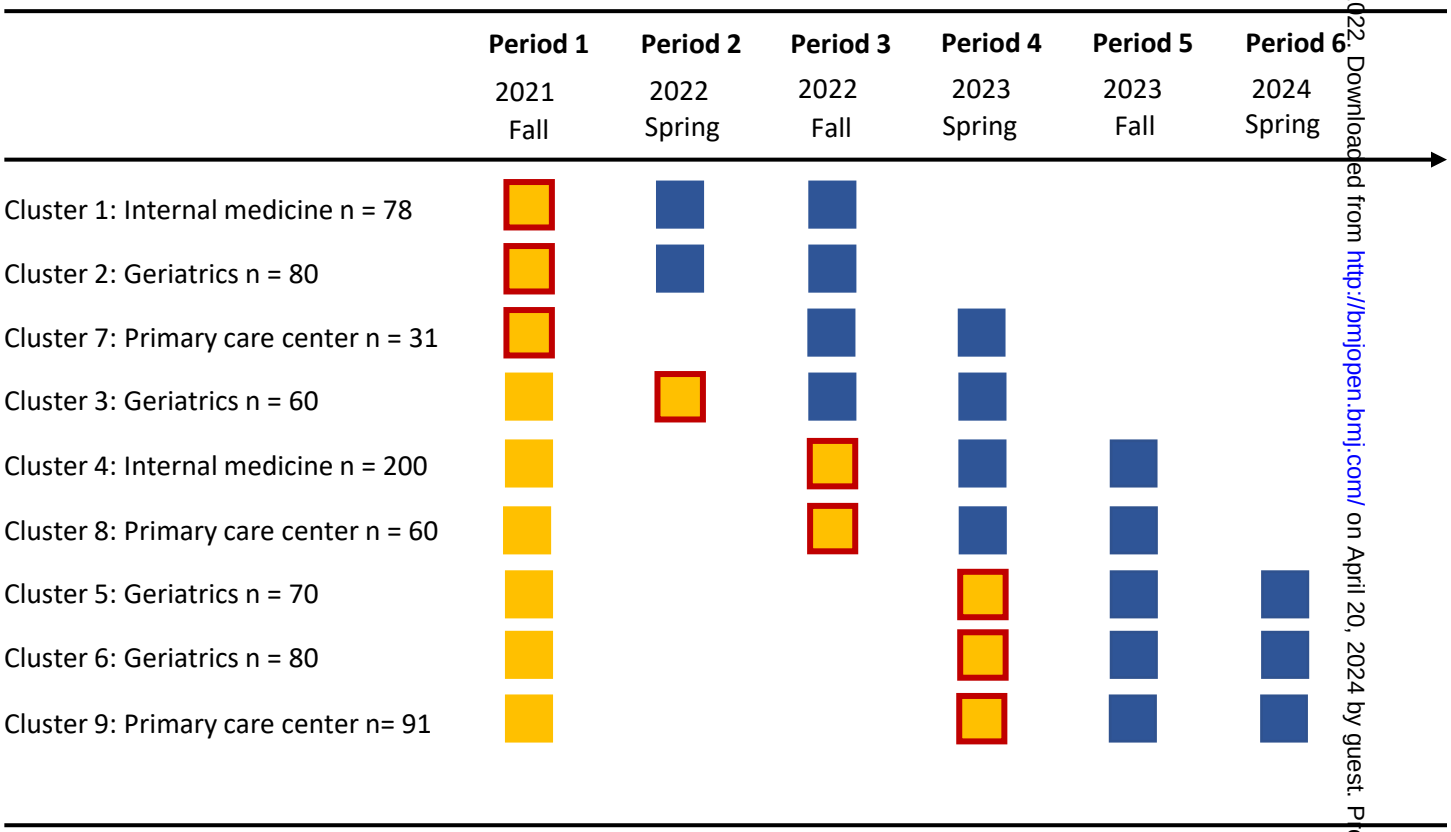




Note: All health care providers participating in the education are eligible to participate in the study, e.g., a person belonging to cluster 4 that do not respond to the baseline (period 1) survey but later partake in the education (period 3) will be asked for inclusion. Meanwhile, a respondent belonging to the same cluster, that participate in the data collection at baseline, but do not attend the education will be excluded. The total anticipated number of participants is around 750

REAGERA-P

(Responding to Elder Abuse in GERiAtric care – Provider questionnaire)

A. Background characteristics

1. **Are you**
   - Female
   - Male
   - Other

2. **How old are you?**
   - Up to 34 years old
   - 35-49 years old
   - 50 years old or older

3. **What is your current profession?**
   - Assistant nurse
   - Nurse
   - Physician
   - Other

4. **How long have you worked in your current profession?**
   - Less than one year
   - 1-5 years
   - 5-10 years
   - More than 10 years

5. **How long have you worked at your current workplace?**
   - Less than one year
   - 1-5 years
   - 5-10 years
   - More than 10 years

6. **Do you work in outpatient or inpatient care?**
   - Only in outpatient care
   - Mainly in outpatient care
   - Equally as much in outpatient and inpatient care
   - Mainly in inpatient care
   - Only in inpatient care

7. **In your education, did you receive training on violence in close relationships (regardless of age) or elder abuse?** (Multiple answers possible)
   - Yes, elder abuse
   - Yes, violence in close relationships
   - No
   - Do not remember

8. **Did you at any other time receive training on violence in close relationships (regardless of age) or elder abuse?** (Multiple answers possible)
   - Yes, elder abuse
   - Yes, violence in close relationships
   - No
   - Do not remember

9. **Are you familiar with the Regional guidelines for managing cases of violence in close relationships, including elder abuse?**
   - Yes, I have used them in my work
   - Yes, I have read parts of it or the entire guideline, but never used it
   - Yes, I know it exists but have not read it nor used it in my work
   - No

10. **Are there written local guidelines for managing cases of violence in close relationships or elder abuse where you work?**
    - Yes, elder abuse
    - Yes, violence in close relationship
    - No
    - I don't know

11. **To what extent do you feel that it is OK at your workplace to question the managers how you work, or to point out shortcomings in the activities?**
    - to a large extent
    - To a somewhat large extent
    - To some extent
    - To a small extent

12. **To what extent do you feel that the employees at your workplace seek help from each other if there is something they do not know how to do, or that they have the courage to say if they feel uncertain about something or have made a mistake?**
    - to a large extent
    - To a somewhat large extent
    - To some extent
    - To a small extent

Elder abuse is defined by the WHO in the following way:

"Elder Abuse is a single or repeated act, or lack of appropriate action, occurring within any relationship where there is an expectation of trust which causes harm or distress to an older person."

Elder abuse include:

- physical, emotional and sexual violence or abuse
- financially exploitation
- neglect

By older, we mean individuals over 65 years of age.

By "asking questions about abuse", we mean that you directly ask if the patient has been treated badly or subjected to some kind of abuse. Accordingly, we do not mean general questions about circumstances at home or how they are doing.

This applies to the entire questionnaire.

B. Case vignette

You will now be asked to read a patient case. In your work, what would you think about asking this patient questions about abuse in different phases of your contact?

Gunnel, aged 77, is admitted to the hospital due to a deterioration of her COPD. Her breathing rapidly improves, but Gunnel instead complains a lot about abdominal pain. She has sought care for this several times both at the health care centre and the emergency ward, but the pain does not improve. She previously underwent a thorough investigation, including gastroscopy, without any explanation for the symptoms being found.

[Alternative text for those working at aprimary health care centre: Gunnel, aged 77, has recently registered with the health care centre and you meet her for the first time for an annual exam of her COPD. It seems to be well-managed, but Gunnel instead complains a lot about abdominal pain.]

13. How likely is it, based solely on this information, that you ask Gunnel questions about abuse?

- Not at all likely
- Not particularly likely
- Somewhat likely
- Very likely

In the conversation, it comes forth that Gunnel in recent years has sought care on multiple occasions with different symptoms, but no good explanation has been found for her symptoms. Among other things, she was treated for chest pain that was not deemed to be cardiac related, and she has had very troublesome back pain for an unclear reason.

14. Based on the information you now have access to, how likely is it that you ask Gunnel questions about abuse?

- Not at all likely
- Not particularly likely
- Somewhat likely
- Very likely

Before the next time you see Gunnel, you see in the medical records that she has been depressed periodically. Last year, she received in-patient care over 24 hours because she had taken too many of her antidepressive pills. In the medical record, it says that the overdose was probably happened by mistake, but that the circumstances were a little unclear. After that care episode, Gunnel received Apodos so that it would not happen again.

15. Based on the information you now have access to, how likely is it that you ask Gunnel questions about abuse?

- Not at all likely
- Not particularly likely
- Somewhat likely
- Very likely

Gunnel says that she is single and lives in a villa. She has handled it well so far, but she says that she would need home-help services now to be able to manage everything. Gunnel has a son who lives in the same city and he has financial problems and therefore lives with Gunnel now and then. When you see

Gunnel, you ask if she likes having her son living with her sometimes. Gunnel answers vaguely and evasively. A few days later, a needs assessment is done and the son then says that he thinks it is unnecessary to spend money on the home-help services, and Gunnel agrees. Afterwards, you meet Gunnel alone again.

16. **Based on the information you now have access to, how likely is it that you ask Gunnel questions about abuse?**
    - Not at all likely
    - Not particularly likely
    - Somewhat likely
    - Very likely

You now also examine Gunnel again and note something that you had not seen before. She has older bruises on both upper arms. When you ask what happened, Gunnel tries to joke the question away and says that she does not know, but that she might have "happened to bump into something".

17. **Based on the information you now have access to, how likely is it that you ask Gunnel questions about abuse?**
    - Not at all likely
    - Not particularly likely
    - Somewhat likely
    - Very likely

C. Cause for concern

How concerned are you about the following things when it comes to asking older patients questions about abuse?

18. **That I will not be able to offer the patient a good follow-up**
    - Not at all concerned
    - A little concerned
    - Somewhat concerned
    - Very concerned

19. **That the patient reacts negatively if I ask questions**
    - Not at all concerned
    - A little concerned
    - Somewhat concerned
    - Very concerned

20. **That the patient-care provider relationship will be negatively impacted if I ask questions**
    - Not at all concerned
    - A little concerned
    - Somewhat concerned
    - Very concerned

D. Self-efficacy

21. At present, how would you manage to do the following things in your work?

	Would magage it very poorly 0	1	2	3	4	5	6	7	8	9	Would manage it very well 10
a. Asking questions about abuse to an older patient who has clear indications of now being, or having previously been, subjected to abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. Asking questions about abuse to an older patient who has no clear indications of now being or having previously been, subjected to abuse.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. Ensuring you are able to ask questions about abuse in private to an older patient who has a relative who insists on being present during all contact	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
d. In conversation, providing support to an older patient who tells about abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
e. Helping an older patient subjected to abuse on to the right body in healthcare, or to the right support function in society	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
f. Helping an older patient subjected to abuse to make a report to the police or social services	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
g. Helping and supporting an older patient subjected to abuse, who does not currently want to change his or her situation	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
h. Handling the meeting with an older patient who says no to questions about abuse, but where you still have strong suspicions that the patient is subjected to abuse.	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

E. Own previous experiences

22. To what extent do you feel that you can assess the likelihood that an older patient was subjected to abuse without having to ask specific questions?

- To a large extent
- To a somewhat large extent
- To some extent
- To a small extent

23. Approximately how many times in the past six months has an older patient spontaneously told you about experiencing abuse, without you asking questions about it?

- None
- 1 time
- 2 times
- 3 times
- 4 times
- 5 times
- 6 times
- 7 times
- 8 times
- 9 times
- 10 times or more

24. Approximately how many times have you asked older patients questions about abuse in the past six months?

- None
- 1 time
- 2 times
- 3 times
- 4 times
- 5 times
- 6 times
- 7 times
- 8 times
- 9 times
- 10 times or more

25. Approximately how many times did the questions lead to an older patient telling about abuse that he or she experienced?

- None
- None
- 1 time
- 2 times
- 3 times
- 4 times
- 5 times
- 6 times
- 7 times
- 8 times
- 9 times
- 10 times or more

26. Have you at any time had lingering suspicions that the patient is or has been subjected to abuse even though he or she has denied it when you asked questions about it?

- No
- Yes, once
- Yes, several times

27. Feel free to tell a little about one such situation:

28. Think about the last time an older patient told you about abuse. *To what extent do you think that the patient received a good follow-up?*

- Not at all
- To a small extent
- To some extent
- To a somewhat large extent
- To a large extent
- To a very large extent
- The patient was deemed not to need follow-up
- The patient was offered follow-up, but turned it down
- Cannot assess how the follow-up turned out

29. Feel free to tell more about the handling here:

30. In the past six months, have you had suspicions that an older patient was subjected to abuse, but did not ask questions about it?

- I have not had any such suspicions
- I have had suspicions, but did not ask any questions
- I have always asked questions if I had suspicions
- Do not remember

31. What was it that led to you not asking questions? (Multiple answers possible)

- The suspicions were not strong enough
- I was uncertain about how to ask questions
- I was uncertain about how to handle the answer
- I have too little professional experience to ask questions
- I thought it was somebody else's responsibility to ask questions
- I raised the issue with colleagues and somebody else asked questions
- I raised the issue with colleagues, but it did not lead to anyone asking questions
- Another reason, namely:

F. Sense of responsibility

32. How much responsibility do you think that the health care services, have for identifying older patients who currently are, or have previously been, subjected to abuse?

- None
- Little
- Rather little
- Quite a lot
- A lot
- Very much

33. How much responsibility do you think that you, in your professional role have for identifying older patients who currently are, or have previously been, subjected to abuse?

- None
- Little
- Fairly little
- Quite a lot
- A lot
- Very much

34. How much responsibility do you think the following professional categories have at your workplace for asking older patients questions about abuse?

	None	Little	Fairly little	Quite a lot	A lot	Very much
Nurse	☐	☐	☐	☐	☐	☐
Assistant nurse	☐	☐	☐	☐	☐	☐
Counsellor and psychologist	☐	☐	☐	☐	☐	☐
Physician	☐	☐	☐	☐	☐	☐
Other professions	☐	☐	☐	☐	☐	☐

G. Attitude towards routinely asking questions

To what extent do you feel that you at your workplace should strive to routinely ask questions about abuse to the following patient groups?

35. All older patients with certain diagnoses or symptoms (e.g. depression or indistinct pain)

- Not at all
- To a small extent
- To some extent
- To a somewhat large extent
- To a large extent
- To a very large extent

36. All older patients who seek care with symptoms for which no medical explanation is found

- Not at all
- To a small extent
- To some extent
- To a somewhat large extent
- To a large extent
- To a very large extent

37. All older patients

- Not at all
- To a small extent
- To some extent
- To a somewhat large extent
- To a large extent
- To a very large extent

H. Perceived barriers

To what extent do you think that, at your workplace, the following factors prevent you from asking older patients questions about abuse?

38. Lack of time

- Not at all
- To a small extent
- To some extent
- To a somewhat large extent
- To a large extent
- To a very large extent

39. My own insufficient awareness of the problem

- Not at all
- To a small extent
- To some extent
- To a somewhat large extent
- To a large extent
- To a very large extent

40. Inadequate routines at the workplace for asking questions

- Not at all
- To a small extent
- To some extent
- To a somewhat large extent
- To a large extent
- To a very large extent

41. Inadequate routines at the workplace for handling the answer

- Not at all
- To a small extent
- To some extent
- To a somewhat large extent
- To a large extent
- To a very large extent

42. If you would like help to handle the situation when an older patient tells you about abuse, do you know who at your workplace you could turn to?

- Yes
- No

43. How do you think the preparedness at your workplace is for taking care of older patients subjected to abuse?

- Very good
- Fairly good
- Somewhat inadequate
- Very inadequate
- Don't know what preparedness there is

44. How do you think the preparedness in society is for taking care of older patients subjected to abuse?

- Very good
- Fairly good
- Somewhat inadequate
- Very inadequate
- Don't know what preparedness there is

45. Do you know what you should do to document what patients tell you about abuse in a correct and secure way in the medical record?

- Absolutely
- To a large extent
- To some extent
- Not really

46. Do you think you have enough legal knowledge, for example about when and to whom one can/must report if an older patient is mistreated and what secrecy rules apply?

- Absolutely
- To a large extent
- To some extent
- Not really

I. Own exposure to violence

Below are some concluding questions of a more personal nature. They are about your own possible experiences of having been subjected to abuse in life. We are asking the questions to be able to investigate if there is an association between what one has personally experienced in life and how one relates to older patients who have been subjected to abuse. As for other questions in the questionnaire, your responses are personal, but all analyses are done on a group level and that is also how the results will be presented.

It is common to have been subjected to some kind of abuse during life. If this is your case and you have a need for support and help to process this, please turn to one of the support services that are described in the folder you received in connection with the training day. [Alternative text control group**: …**in the folder you received in connection with the invitation to participate in the study.]

If you do not want to answer these questions, you may opt to pass by them one by one.

47. Have you yourself, as a child or as an adult, been subjected to any kind of physical abuse?
Such as being beaten, kicked, forcibly held or subjected to other physical violence that you perceived as frightening

- No
- Yes, as a child (<18 years)
- Yes, as an adult (≥18 years)

47b. Who subjected you to abuse as an adult (≥18 years)?

- A partner or former partner
- A family member or relative
- Another person I knew
- A completely unknown person

47c. Who subjected you to abuse as a child (<18 years)?

- A partner or former partner
- A family member or relative
- Another person I knew
- A completely unknown person

48. Have you yourself, as a child or as an adult, been subjected to any kind of sexual abuse?
Such as somebody touching your body against your will or forcing you to perform sexual acts

- No
- Yes, as a child (<18 years)
- Yes, as an adult (≥18 years)

48b. Who subjected you to abuse as an adult (≥18 years)?

- A partner or former partner
- A family member or relative
- Another person I knew
- A completely unknown person

48c. Who subjected you to abuse as a child (<18 years)?

- A partner or former partner
- A family member or relative
- Another person I knew
- A completely unknown person

49. Have you yourself, as a child or as an adult, been subjected to any kind of emotional abuse? For example, that somebody repeatedly degraded you, humiliated you or tried to limit your contact with others or decide what you may and may not do

- No
- Yes, as a child (<18 years)
- Yes, as an adult (≥18 years)

49b. Who subjected you to abuse as an adult (≥18 years)?

- A partner or former partner
- A family member or relative
- Another person I knew
- A completely unknown person

49c. Who subjected you to abuse as a child (<18 years)?

- A partner or former partner
- A family member or relative
- Another person I knew
- A completely unknown person

50. Have you yourself, as a child or at an adult age, been subjected to any kind of financial or material abuse? For example, that somebody exploited you financially or took control of your finances

- No
- Yes, as a child (<18 years)
- Yes, as an adult (≥18 years)

50b. Who subjected you to abuse as an adult (≥18 years)?

- A partner or former partner
- A family member or relative
- Another person I knew
- A completely unknown person

50c. Who subjected you to abuse as a child (<18 years)?

- A partner or former partner
- A family member or relative
- Another person I knew
- A completely unknown person

NOTE:

This questionnaire is a further development of the Responding to Elder Abuse in GERiAtric care – provider questionnaire, previously published under a creative common attribution 4.0 license.

Reference: Simmons, J., Wenemark, M. & Ludvigsson, M. Development and validation of REAGERA-P, a new questionnaire to evaluate health care provider preparedness to identify and manage elder abuse. BMC Health Serv Res 21, 473 (2021). https://doi.org/10.1186/s12913-021-06469-2.

Some items (19, 23-30, 31-38 and 44-47) were not included in the original study but was added for a pilot test of an educational model about elder abuse. A preprint of that study is available under a creative common attribution 4.0 licence.

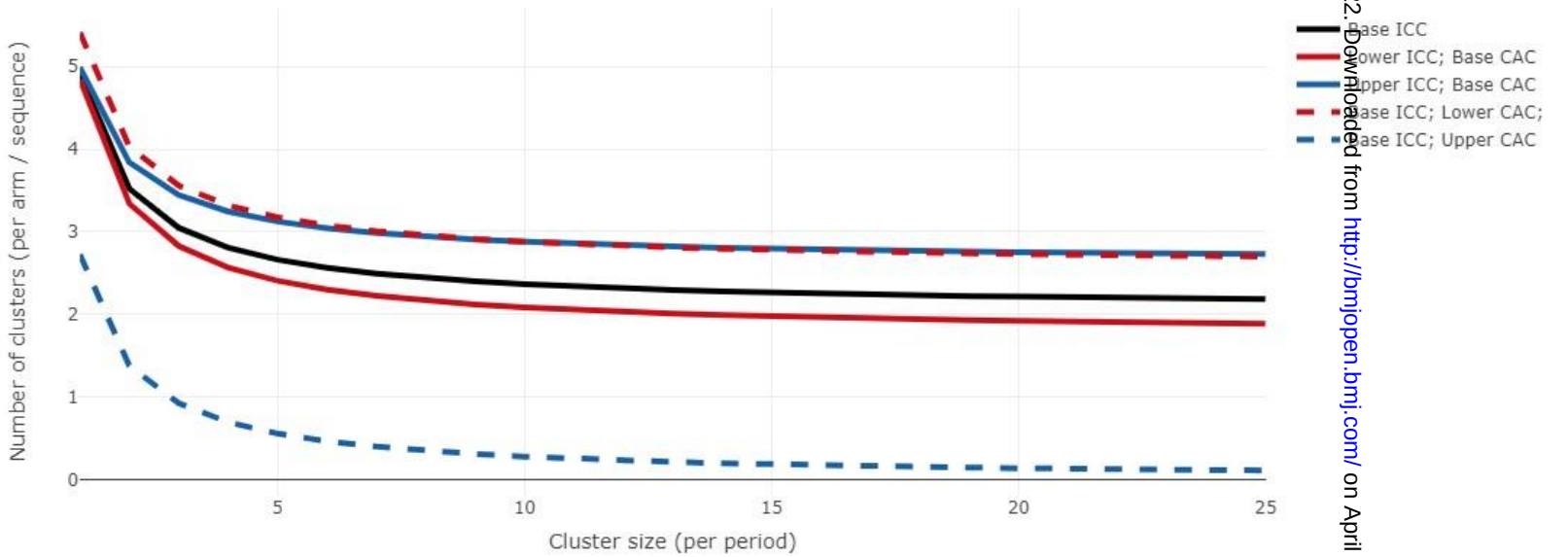
Reference: Simmons J, Motamedi A, Ludvigsson M, Swahnberg K. Testing an educational intervention to improve health care providers' preparedness to care for victims of elder abuse. A mixed method pilot study. Research Square [Preprint]. 2022. [Accessed 2022 April 2] https://doi.org/10.21203/rs.3.rs-1510390/v1

Compared to the previously used versions of REAGERA-P, the following minor changes were made in the current version:

- *Items no 6, 9, 10 concerning background characteristics were added.*
- *The word "approximately" was added to questions 23-25 and the wording of question 32-33 were slightly modified to increase readability.*
- *For items 4-5, 23-25, 28 and 32-41 the response categories have been modified so that more response categories were added, in most cases turning a four-point ordinal scale into a six-point scale.*

Additional file 2. Sample size calculation.

Trade off | Design matrix | References and Contacts



Curve shows the reduction in number of clusters required as cluster-period size increases (for a fixed power).

Warning: caution is needed with CRTs with a small number of clusters due to risk of lack of internal and external validity; and appropriateness of calculations used particularly for binary and count outcomes

Parameters

Power: 0.8

p0: 0.25 p1: 0.56

Significance level: 0.05

Number of sequences: 4

WP-ICC: 0.4 WP-ICC (lower): 0.34 WP-ICC (upper): 0.51 CAC: 0.6

Individual auto-correlation: 0.6

Förfrågan om medverkan i forskningsstudie om sjukvårdens ansvar i mötet med utsatta äldre

Vi vill fråga dig om du vill delta i ett forskningsprojekt. I det här dokumentet får du information om projektet och om vad det innebär att delta.

Vad är det för projekt och varför vill ni att jag ska delta?

Det är relativt vanligt att äldre män och kvinnor är, eller har varit, utsatta för kränkningar, våld och/eller övergrepp. Att ha varit utsatt för sådana negativa händelser kan påverka hälsan. REAGERA (Responding to Elder Abuse in GERiAtric care) är ett forskningsprojekt vars långsiktiga mål är att förbättra vårdens omhändertagande av äldre utsatta för övergrepp.

Under kommande utbildningsdagkommer du få vara med om en heldagsutbildning som handlar om äldres utsatthet för övergrepp och det ansvar som hälso- och sjukvårdspersonal har i mötet med patienter som är eller har varit utsatta för övergrepp. Utbildningsinsatsen vänder sig till personal som i sitt arbete möter äldre patienter. Alla som inbjuds att delta i utbildningen tillfrågas också om att delta i forskningsprojektet vars syfte är att undersöka effekten av utbildningsinsatsen.

Forskningshuvudman för projektet är Region Östergötland.

Hur går studien till?

Att delta innebär att svara på den webenkät du kommer till om du klickar på länken i slutet på detta brev, vilket beräknas ta mellan 5 och 15 minuter. Frågorna handlar om sjukvårdens arbete med äldre utsatta för övergrepp och dina egna erfarenheter av att möta utsatta äldre. Du kommer även få förfrågningar om att svara på uppföljande webenkäter. Ett mindre antal personer kommer också att tillfrågas om att delta i en intervjustudie. Förfrågan om deltagande i denna studie kommer att skickas ut separat och även om du svarar på enkäten kan du tacka nej till att delta i intervjun. Du kan också låta bli att svara på enkäten men ändå tacka ja till att delta i intervjustudien. Oavsett om du väljer att vara med i någon del av studien eller inte kommer du erbjudas att vara med på utbildningsdagen.

Möjliga följder och risker med att delta i studien

Studien berör ett ämne, övergrepp mot äldre, som kan väcka känslor och eventuellt obehag. Om du har behov av stöd och hjälp för att hantera detta finns bifogat ett informationsblad med viktiga instanser i samhället dit man kan vända sig för att få hjälp. Detta gäller både om man själv är eller har varit utsatt för övergrepp, om det handlar om en anhörig eller om du har frågor kring hur du kan hjälpa en patient.

Vad händer med mina uppgifter?

Projektet kommer att samla in och registrera information om dig. Den information vi kommer ha tillgång till och spara är den som du lämnar i dina svar i webenkäten. Dina svar i webenkäten är personliga för att vi ska kunna följa utvecklingen över tid. Alla resultat som offentliggörs kommer dock redovisas på gruppnivå. Vi behandlar informationen om dig i forskningssyfte vilket är av allmänt intresse och anledningen till att vi får behandla informationen enligt gällande lagstiftning.

Datamaterialet kommer att förvaras så att inga obehöriga kan ta del av dem och lagras under minst 10 år. Under datainsamlingsperioden kommer data hanteras av företaget Webropol. Därefter kommer grunddata och kodnyckel förvaras i en mapp på Region Östergötlands intranät som bara forskargruppen har tillgång till. Kodade datafiler kommer också hanteras inom Linköpings Universitets datasystem.

Dina svar och dina resultat kommer att behandlas så att inte obehöriga kan ta del av dem.

Ansvarig för dina personuppgifter är Region Östergötland. Enligt EU:s dataskyddsförordning har du rätt att kostnadsfritt få ta del av de uppgifter om dig som hanteras i studien, och vid behov få eventuella fel rättade. Du kan också begära att uppgifter om dig raderas samt att behandlingen av dina personuppgifter begränsas. Om du vill ta del av uppgifterna ska du kontakta Johanna Simmons, johanna.simmons@regionostergotland.se telefon 010-1031057. Dataskyddsombud nås via e-post: dataskyddsombud@regionostergotland.se. Om du är missnöjd med hur dina personuppgifter behandlas har du rätt att ge in klagomål till Datainspektionen, som är tillsynsmyndighet.

Hur får jag information om resultatet av studien?

Resultatet kommer användas för forskningsändamål samt som underlag i utvecklingsarbete och presenteras i vetenskapliga rapporter och tidskrifter. Du är välkommen att kontakta forskningsledaren, Johanna Simmons, johanna.simmons@regionostergotland.se om du vill ha tillgång till dina egna individuella data eller resultatet av hela studien.

Försäkring och ersättning

Ingen ytterligare försäkring än de som arbetsgivaren tillhandahåller anställda har tecknats för deltagande i studien.

Ingen ekonomisk ersättning utgår för deltagande i studien.

Deltagandet är frivilligt

Ditt deltagande är frivilligt och du väljer själv vilka frågor i webenkäten du vill svara på. Det är också möjligt att börja svara på enkäten men avbryta utan att skicka in svaren. Om du väljer att inte delta eller vill avbryta ditt deltagande behöver du inte uppge varför, och det kommer inte heller att påverka din möjlighet att delta i utbildningsinsatsen.

Har du frågor om studien?

Om du vill ställa frågor om studien eller någon del av den här informationen innan du bestämmer dig för om du vill delta, kontakta ansvarig forskare enligt nedan.

Ansvarig för studien

Johanna Simmons
Medicine doktor, ST-läkare i geriatrik
Medicinska och geriatriska akutkliniken
Universitetssjukhuset i Linköping
e-post: johanna.simmons@regionostergotland.se
Telefon: 010-1031057

Samtycke till att delta i studien

☐ Jag samtycker till att delta i studien REAGERA – Sjukvårdens ansvar i mötet med utsatta äldre. Personalintervention.

☐ Jag samtycker till att uppgifter om mig behandlas på det sätt som beskrivs i forskningspersonsinformationen.

Länk till webenkäten

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	14
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	14
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
	6b	Explanation for choice of comparators	4-5

Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-10, Table 1
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 6 and Figure 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11-12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	N/A
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9-10, Table 1, Figure 1, Additional file 1
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	10
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	10-11
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	10-11

	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	10-11
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	12
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	12
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	12
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14

Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	12
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	12
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	14
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Additional file 3
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.