

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-060314
Article Type:	Protocol
Date Submitted by the Author:	20-Dec-2021
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 Simmons, Johanna; Linköping University, Department of Acute Internal Medicine and Geriatrics, and Department of Health, Medicine and Caring Sciences
Keywords:	EDUCATION & TRAINING (see Medical Education & Training), GERIATRIC MEDICINE, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, MEDICAL EDUCATION & TRAINING

SCHOLARONE™
Manuscripts

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

Authors:

Mikael Ludvigsson, MD, PhD ^{1,2}

Atbin Motamedi, MD ³

Björn Westerlind, MD, PhD ^{4,5}

Johanna Simmons, MD, PhD (corresponding author) ¹

Affiliations:

1. Department of Acute Internal Medicine and Geriatrics, and Department of Health, Medicine and Caring Sciences, Linköping University, Linköping, Sweden
2. Department of Psychiatry, and Department of Biomedical and Clinical Sciences, Linköping University, Linköping, Sweden
3. Department of Emergency Medicine in Norrköping, and Department of Health, Medicine and Caring Sciences, Linköping University, Linköping, Sweden
4. Department of Geriatrics, County Hospital Ryhov, Region Jönköping County, Jönköping, Sweden
5. Department of Health, Medicine and Caring Sciences, Linköping University, Linköping, Sweden

Corresponding author

Johanna Simmons

Postal address: Medicinska och geriatriska akutkliniken, Region Östergötland, 581 91 Linköping, Sweden

Phone: +46 10 103 61 45

Fax: Not available

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.

For peer review only

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

1
2
3 had received any form of training regarding elder abuse. A further 26% had received training about
4 violence in close relationships. However, 48% reported that they had received no training regarding
5 violence and abuse at all, or that they did not remember whether they had received any such
6 training. Having received training was, however, associated with a greater likelihood of reporting
7 experiences of speaking with an older patient about abuse (16).
8
9

10
11
12 There have been relatively few studies of effective ways to train staff about elder abuse. The few
13 studies that have been conducted do show that it is not effective to only hand out information
14 material to staff (18). Rather, interactive training components have been recommended (19). Using
15 patient cases and practical training with real or simulated patients or through virtual reality (VR) has
16 been appreciated by participants (18, 20, 21). It has also previously been highlighted that training
17 should be adapted to local conditions. Being able to give contact details to relevant local
18 organisations for victims is important, so that the training can easily be translated into everyday
19 practice (18).
20
21
22
23
24
25

26
27 In this project, health care professionals will be trained to ask older patients questions about abuse
28 and to better manage the response. The education consists of theory and group discussions as well
29 as forum play, a form of interactive theatre where participants – together with drama teachers –
30 practise dealing with difficult situations and finding alternative ways of acting, as a form of skills
31 training. Forum play has been described as an innovative training model that stimulates reflection
32 and learning within the health care system (22). The method has previously been used for purposes
33 such as training health care staff to counter abuse in health care (22, 23). A pilot study of the
34 proposed training model has been carried out previously, with positive results which will be
35 published separately.
36
37
38
39
40
41

42 Aim

43
44 The overall aim of the project is to increase health care professionals' propensity to ask older
45 patients questions about abusive experiences. More specifically, we will:
46
47

- 48 1) Investigate whether the training changes the propensity to ask questions about abuse.
- 49 2) Investigate whether the training changes a) participants' self-efficacy concerning their own
50 ability to ask questions about abuse and to manage the response, and b) participants'
51 perceived barriers to asking questions on an individual or organisational level.
52
53
54
55
56
57
58
59
60

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

1
2
3 embodied knowledge (27, 28). In order to facilitate transfer to clinical practice, we provide practical
4 advice on questions that can be posed to older patients about abuse, and we present guidelines for
5 what to consider when encountering older adults who have been subjected to different forms of
6 abuse.
7
8
9

10
11 There is no evidence-based practice on how best to manage cases of elder abuse (29, 30). Even so,
12 much can be done on an individual level. The recommendations given during the training day about
13 how to manage cases of elder abuse are largely based on trauma-informed care (31, 32) and on
14 providing information about the different sources of help available to victims in society and in health
15 care.
16
17
18

19 20 21 *Theoretical training (lectures and group discussions)*

22 During the first part of the training day, we use lectures interspersed with video recorded meetings
23 with abuse victims and group discussions. The first and last author are responsible for giving the
24 lectures and leading the group discussions. During the lectures we focus on three themes: 1) What is
25 elder abuse and what is my responsibility as a caregiver when encountering victims of elder abuse?
26 2) How can I ask questions about elder abuse? 3) An older patient told me about abuse – how do I
27 handle the situation? For the second and third themes, we have produced short films that show
28 encounters between health care providers and patients. One film is about asking questions about
29 abuse and another is about handling the response. Two versions of each patient–provider encounter
30 have been filmed in order to show how the different ways staff act affect the encounter with the
31 patient. After viewing each film, the content is discussed in small groups: What went well in the
32 encounter, what went less well and how could we do it differently? During the day, concrete
33 guidance is also offered regarding how to ask questions, and we introduce the screening
34 questionnaire REAGERA-S (33) as a tool to ask older adults about experiences of abuse. We also
35 present local resources and guidelines relating to what staff could consider in terms of handling
36 situations where they encounter victims of elder abuse.
37
38
39
40
41
42
43
44
45
46
47

48 49 *Forum play*

50 The second part of the training day is spent on forum play, a form of participatory theatre developed
51 by Byréus (28), based on Boal's (27) forum theatre. The forum play is led by three drama teachers.
52 Before starting, the participants form small groups to work out case descriptions of care situations
53 pertaining to elder abuse that they themselves have perceived as challenging to deal with. In this
54 way, participants' own experiences and real-world difficulties are used for the training and practical
55 reasoning. Two pre-prepared patient cases based on research and clinical experience of difficulties
56 during encounters with victims of elder abuse are also used. The forum play starts with the drama
57
58
59
60

1
2
3 teachers acting out the different situations, i.e., a staff–patient encounter where something went
4 wrong or was difficult to manage. The situation is then acted out a second time, but this time the
5 participants are invited to influence the encounter themselves. Participants are encouraged to say
6 “stop” when the sequence of events is heading in the wrong direction. A participant then takes over
7 the drama teacher’s role and tries to act in a different way. Alternatively, the participant can give
8 suggestions about how they would like the drama teacher to act differently. Thus, through the forum
9 play, the participants and the drama teachers explore together how their way of acting can influence
10 and improve the encounter with an older patient who has been subjected to abuse. This also reveals
11 how there are alternative ways of acting, which may empower staff to deal with elder abuse. After
12 each scene has been worked through, a brief comment is given concerning suggestions regarding
13 ongoing management of the case, and how to provide help in this specific case. This provides
14 participants with some model cases that they can later relate to when faced with similar situations.

24 *Post-training reflection on changing practices*

25 To further encourage the training being transferred to the participants’ everyday practice, the
26 training ends with a discussion on how to move forward. Can the training and the tools provided be
27 incorporated into clinical routines?
28

31 **Material and analysis**

32 **REAGERA-P** is a validated questionnaire (34) that can be used to measure health care providers’
33 preparedness to ask questions about abuse and manage the response. Figure 2 presents a schematic
34 view of the factors measured in REAGERA-P.
35

36 [insert Figure 2 around here]
37

38 **Retrospective selective review of medical records.** For security reasons, the information about
39 abusive experiences should be documented using specific templates in the medical records that are
40 hidden in the online records. We will search these templates anonymously to investigate how
41 frequent it is for the records at each participating clinic to document that a patient has been the
42 victim of abuse. The validity of this data has not been established, and it will therefore be considered
43 an experimental outcome. However, this could potentially represent an objective assessment of
44 whether the intervention leads to increased identification of patients who have been subjected to
45 elder abuse.
46

47 REAGERA-P will be distributed as an online survey immediately before and after the training day, and
48 also on three more occasions, six months apart. In line with the stepped wedge trial design,
49 participants who originally belong to the control group will later move to the intervention group.
50
51
52
53
54
55
56
57
58
59
60

1
2
3 Information from the medical records is retrieved for six-month periods over the course of the study.
4 See Figure 1 for a schematic overview of times of data collection. All
5
6
7

8 *Outcome measures*

9 **Main outcome:** Changes in asking questions about abuse are measured as follows: 1) Changes in self-
10 reported number of times the professional has asked patients questions about abuse (range 0–10
11 and above) as reported in REAGERA-P. The answers will be analysed both as a dichotomous variable
12 (never/one or more times) and as a continuous variable. 2) Changes in the number of times data
13 about abuse has been entered in the medical records on a clinical level.
14
15
16
17

18 **Secondary outcomes:** 1) Changes in the proportion of respondents reporting that victims of elder
19 abuse were given adequate follow-up. 2) Changes in the proportion of respondents reporting
20 suspicions about elder abuse but refraining from asking questions. 3) Changes in the proportion of
21 respondents reporting a changed working practice at six months follow-up as a result of the
22 education.
23
24
25
26

27 **Secondary outcome and mediating variables:** a) Self-efficacy for asking questions about abuse as
28 well as handling the response. b) Sense of responsibility to ask questions. c) Individual-level
29 perceived barriers to ask questions. d) Organisational-level perceived barriers to ask questions. e)
30 Awareness of elder abuse and attitudes towards asking questions routinely.
31
32
33
34

35 **Covariates** potentially affecting both the intervention effectiveness and the outcome will be
36 considered. These include background characteristics of participants on both individual and group
37 levels, and are described in Figure 2.
38
39
40

41 *Statistical analyses*

42 Factors that will be considered in analyses are described in Figure 2. The potential effect of the
43 intervention is expected to be mediated by one or more of the measures listed as secondary
44 outcomes, as well as the covariates listed. Mixed models for repeated measures will be used to
45 evaluate the outcomes. We will strive for parsimony; analysis will therefore be performed to
46 determine which variables to include in multivariate analysis. Covariates that significantly affect the
47 model will be included and cluster effects will be considered. Assumptions for models will be
48 assessed graphically and, if needed, bootstrapping will be used to ensure model robustness.
49 Subgroup analysis will be performed for each cluster (clinic), and also for type of clinic (internal
50 medicine, geriatrics or primary health care) and profession. Missing data will be analysed and, if
51 appropriate, multiple imputations will be considered.
52
53
54
55
56
57
58
59
60

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.

References

1. Yon Y, Mikton CR, Gassoumis ZD, Wilber KH. Elder abuse prevalence in community settings: a systematic review and meta-analysis. *The Lancet Global Health*. 2017;5(2):e147-e56.
2. Pillemer K, Burnes D, Riffin C, Lachs MS. Elder Abuse: Global Situation, Risk Factors, and Prevention Strategies. *The Gerontologist*. 2016;56(Suppl_2):S194-S205.
3. Yon Y, Ramiro-Gonzalez M, Mikton CR, Huber M, Sethi D. The prevalence of elder abuse in institutional settings: a systematic review and meta-analysis. *European Journal of Public Health*. 2018;29(1):58-67.
4. WHO. The Toronto Declaration on the Global Prevention of Elder Abuse. 2002.
5. Storey JE. Risk factors for elder abuse and neglect: A review of the literature. *Aggress Violent Beh*. 2020;50:101339.
6. Dong X, Simon MA. Elder abuse as a risk factor for hospitalization in older persons. *JAMA internal medicine*. 2013;173(10):911-7.
7. Dong XQ. Elder Abuse: Systematic Review and Implications for Practice. *Journal of the American Geriatrics Society*. 2015;63(6):1214-38.
8. Olomi JM, Wright NM, Hasche L, DePrince AP. After Older Adult Maltreatment: Service Needs and Barriers. *Journal of Gerontological Social Work*. 2019;62(7):749-61.

- 1
2
3 9. Burnes D, Acierno R, Hernandez-Tejada M. Help-Seeking Among Victims of Elder
4 Abuse: Findings From the National Elder Mistreatment Study. *J Gerontol B Psychol Sci Soc Sci*.
5 2019;74(5):891-6.
6
7
- 8 10. Lachs MS, Pillemer KA. Elder Abuse. *The New England journal of medicine*.
9 2015;373(20):1947-56.
10
- 11 11. Dow B, Gahan L, Gaffy E, Joosten M, Vrantsidis F, Jarred M. Barriers to Disclosing Elder
12 Abuse and Taking Action in Australia. *J Fam Violence*. 2020;35(8):853-61.
13
- 14 12. Fraga Dominguez S, Storey JE, Glorney E. Help-Seeking Behavior in Victims of Elder
15 Abuse: A Systematic Review. *Trauma Violence Abuse*. 2021;22(3):466-80.
16
- 17 13. Socialdepartementet. Nationell strategi om våld mot äldre personer inom vård och
18 omsorg, Bilaga till protokoll vid regeringssammanträde 2014-06-12 nr II:15 2014.
19
- 20 14. Simmons J, Swahnberg K. Characteristics Associated With Being Asked About Violence
21 Victimization in Health Care: A Swedish Random Population Study. *Journal of Interpersonal Violence*.
22 2020;0(0):0886260520977836.
23
- 24 15. Touza Garma C. Influence of health personnel's attitudes and knowledge in the
25 detection and reporting of elder abuse: An exploratory systematic review. *Psychosocial Intervention*.
26 2017;26(2):73-91.
27
- 28 16. Motamedi A, Ludvigsson M, Simmons J. Factors associated with health care providers
29 speaking with older patients about being subjected to abuse. *Journal of elder abuse & neglect*.
30 2021:1-18.
31
- 32 17. Hoover RM, Polson M. Detecting elder abuse and neglect: assessment and
33 intervention. *Am Fam Physician*. 2014;89(6):453-60.
34
- 35 18. Alt KL, Nguyen AL, Meurer LN. The Effectiveness of Educational Programs to Improve
36 Recognition and Reporting of Elder Abuse and Neglect: A Systematic Review of the Literature. *Journal*
37 *of elder abuse & neglect*. 2011;23(3):213-33.
38
- 39 19. Mohd Mydin FH, Yuen CW, Othman S. The Effectiveness of Educational Intervention in
40 Improving Primary Health-Care Service Providers' Knowledge, Identification, and Management of
41 Elder Abuse and Neglect: A Systematic Review. *Trauma, Violence, & Abuse*.
42 2019:1524838019889359.
43
- 44 20. Pickering CEZ, Ridenour K, Salaysay Z, Reyes-Gastelum D, Pierce SJ. EATI Island – A
45 virtual-reality-based elder abuse and neglect educational intervention. *Gerontology & Geriatrics*
46 *Education*. 2018;39(4):445-63.
47
- 48 21. Fisher JM, Rudd MP, Walker RW, Stewart J. Training Tomorrow's Doctors to Safeguard
49 the Patients of Today: Using Medical Student Simulation Training to Explore Barriers to Recognition
50 of Elder Abuse. *Journal of the American Geriatrics Society*. 2016;64(1):168-73.
51
52
53
54
55
56
57
58
59
60

- 1
- 2
- 3 22. Bruggemann AJ, Persson A. Using forum play to prevent abuse in health care
- 4 organizations: A qualitative study exploring potentials and limitations for learning. *Education for*
- 5 *health* (Abingdon, England). 2016;29(3):217-22.
- 6
- 7
- 8 23. Swahnberg K, Zbikowski A, Wijewardene K, Josephson A, Khadka P, Jeyakumaran D, et
- 9 al. Can Forum Play Contribute to Counteracting Abuse in Health Care? A Pilot Intervention Study in
- 10 Sri Lanka. *International Journal of Environmental Research and Public Health*. 2019;16(9):1616.
- 11
- 12
- 13 24. Brown CA, Lilford RJ. The stepped wedge trial design: a systematic review. *BMC*
- 14 *Medical Research Methodology*. 2006;6(1):54.
- 15
- 16 25. Copas AJ, Lewis JJ, Thompson JA, Davey C, Baio G, Hargreaves JR. Designing a stepped
- 17 wedge trial: three main designs, carry-over effects and randomisation approaches. *Trials*.
- 18 2015;16(1):352.
- 19
- 20
- 21 26. Biggs J. Enhancing teaching through constructive alignment. *Higher Education*.
- 22 1996;32(3):347-64.
- 23
- 24
- 25 27. Boal A. *Theatre of the oppressed*. London: Pluto Press; 2000.
- 26
- 27 28. Byréus K. *Du har huvudrollen i ditt liv: om forumspel som pedagogisk metod för*
- 28 *frigörelse och förändring*. Stockholm: Liber; 2010.
- 29
- 30 29. Fearing G, Sheppard CL, McDonald L, Beaulieu M, Hitzig SL. A systematic review on
- 31 community-based interventions for elder abuse and neglect. *Journal of elder abuse & neglect*.
- 32 2017;29(2-3):102-33.
- 33
- 34
- 35 30. Baker PR, Francis DP, Mohd Hairi NN, Othman S, Choo WY. Interventions for
- 36 preventing elder abuse: applying findings of a new Cochrane review. *Age and ageing*. 2016;46(3):346-
- 37 8.
- 38
- 39
- 40 31. Ernst JS, Maschi T. Trauma-informed care and elder abuse: a synergistic alliance.
- 41 *Journal of elder abuse & neglect*. 2018;30(5):354-67.
- 42
- 43 32. Substance Abuse and Mental Health Services Administration (SAMHSA). *Trauma-*
- 44 *informed care in behavioral health services. Treatment Improvement Protocol (TIP) Series 57*.
- 45 Rockville, MD. : US Department of Health Human Services; 2014. Contract No.: HHS Publication No
- 46 (SMA) 14-4816.
- 47
- 48
- 49
- 50 33. Simmons J, Wiklund N, Ludvigsson M, Nägga K, Swahnberg K. Validation of REAGERA-
- 51 S: a new self-administered instrument to identify elder abuse and lifetime experiences of abuse in
- 52 hospitalized older adults. *Journal of elder abuse & neglect*. 2020;32(2):173-95.
- 53
- 54
- 55 34. Simmons J, Wenemark M, Ludvigsson M. Development and validation of REAGERA-P, a
- 56 new questionnaire to evaluate health care provider preparedness to identify and manage elder
- 57 abuse. *BMC Health Serv Res*. 2021;21(1):473.
- 58
- 59
- 60

1
2
3 35. Hemming K, Kasza J, Hooper R, Forbes A, Taljaard M. A tutorial on sample size
4 calculation for multiple-period cluster randomized parallel, cross-over and stepped-wedge trials
5 using the Shiny CRT Calculator. *International Journal of Epidemiology*. 2020;49(3):979-95.
6
7
8

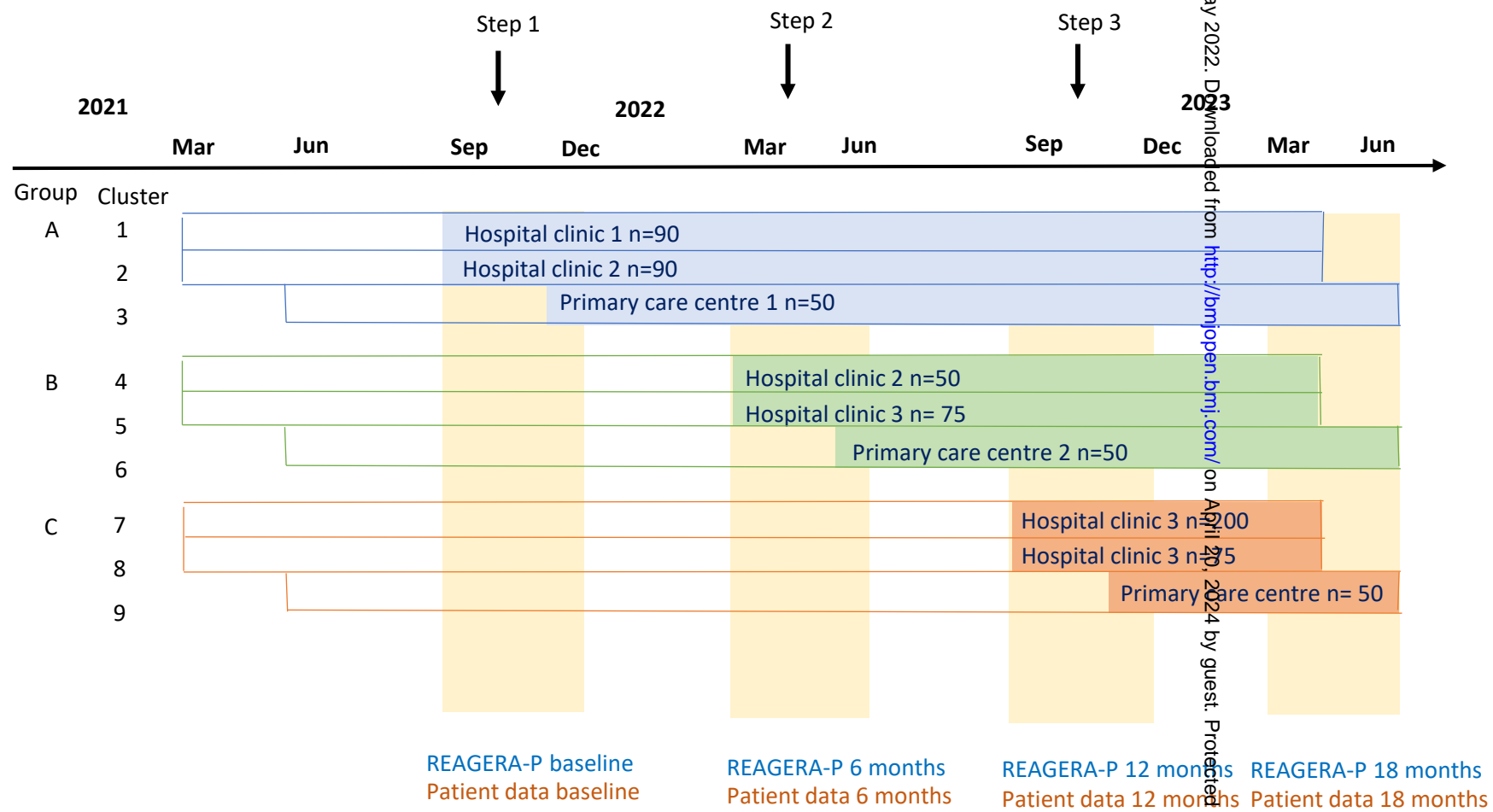
9 Figure legends

10
11
12

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.
13
14
15
16
17
18

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.
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

2021-060314 on 4 May 2022. Downloaded from <http://bmjopen.bmj.com/> on April 20, 2024 by guest. Protected by copyright.



21-060314 on 4 March 2022. Downloaded from http://bmjopen.bmj.com/ on April 29, 2022. Requested by copyright.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41

Intervention

Asking about elder abuse

Secondary outcomes:

- Reporting that identified cases were given an adequate follow-up.
- Reporting suspecting elder abuse but refraining from asking questions
- Reporting changed practice as a result of the intervention

Own evaluation of the intervention

Self-efficacy

- Self-efficacy for asking questions
- Self-efficacy for managing the response

Awareness and attitudes towards asking questions

- Case description
- Attitude towards routinely enquiring about elder abuse

Individual barriers

- Concern about effect on relationship
- Concern about negative patient reaction
- Lack of awareness
- Knowledge about proper documentation routines
- Knowledge about judicial concerns
- Know which colleague to ask for advice

Organisational barriers

- Lack of time
- Deficient routines for asking questions
- Deficient routines for managing the response
- Concern about not being able to give proper follow-up
- Preparedness at the clinic

Responsibility

- Own responsibility
- Own profession's responsibility
- Health care responsibility

Background characteristics – group level

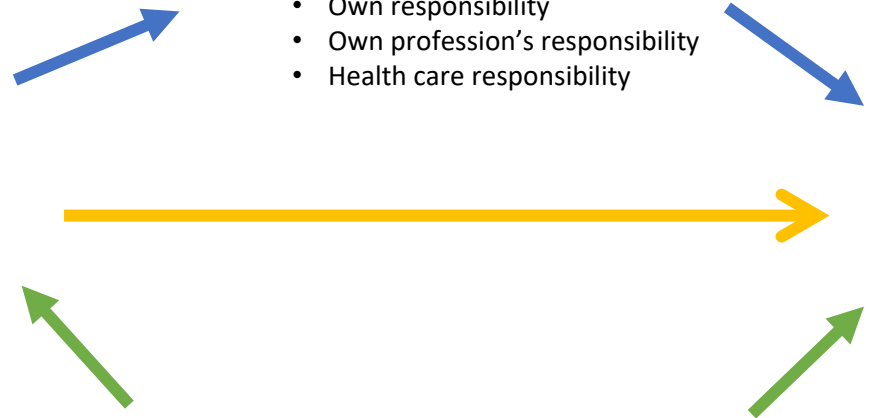
- Clinic/cluster
- Type of clinic (internal medicine, geriatrics, primary care)
- Formal guidelines available
- Working climate at the workplace

Background characteristics – individual level

- Sex
- Age
- Profession
- Years working in profession
- Previous education about elder abuse or violence in close relationships
- Previous experiences of talking to patients about elder abuse
- Knowledge about available formal guidelines - baseline
- Own abusive history

Societal level barriers

- Preparedness in society





STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Section/item	Item number	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

1			
2	Objectives	7	Specific objectives or hypotheses
3			4
4	Trial	8	Description of trial design including type of trial (eg, parallel
5	design		group, crossover, factorial, single group), allocation ratio, and
6			framework (eg, superiority, equivalence, noninferiority,
7			exploratory)
8			
9			
10	Methods: Participants, interventions, and outcomes		
11			
12	Study	9	Description of study settings (eg, community clinic, academic
13	setting		hospital) and list of countries where data will be collected.
14			Reference to where list of study sites can be obtained
15			
16	Eligibility	10	Inclusion and exclusion criteria for participants. If applicable,
17	criteria		eligibility criteria for study centres and individuals who will perform
18			the interventions (eg, surgeons, psychotherapists)
19			
20			
21	Interventio	11a	Interventions for each group with sufficient detail to allow
22	ns		replication, including how and when they will be administered
23			
24		11b	Criteria for discontinuing or modifying allocated interventions for a
25			given trial participant (eg, drug dose change in response to
26			harms, participant request, or improving/worsening disease)
27			
28		11c	Strategies to improve adherence to intervention protocols, and
29			any procedures for monitoring adherence (eg, drug tablet return,
30			laboratory tests)
31			
32			
33		11d	Relevant concomitant care and interventions that are permitted or
34			prohibited during the trial
35			
36	Outcomes	12	Primary, secondary, and other outcomes, including the specific
37			measurement variable (eg, systolic blood pressure), analysis
38			metric (eg, change from baseline, final value, time to event),
39			method of aggregation (eg, median, proportion), and time point
40			for each outcome. Explanation of the clinical relevance of chosen
41			efficacy and harm outcomes is strongly recommended
42			
43			
44	Participant	13	Time schedule of enrolment, interventions (including any run-ins
45	timeline		and washouts), assessments, and visits for participants. A
46			schematic diagram is highly recommended (see Figure)
47			
48			
49	Sample	14	Estimated number of participants needed to achieve study
50	size		objectives and how it was determined, including clinical and
51			statistical assumptions supporting any sample size calculations
52			
53	Recruitme	15	Strategies for achieving adequate participant enrolment to reach
54	nt		target sample size
55			5

Methods: Assignment of interventions (for controlled trials)

Allocation:

1				
2	Sequen	16a	Method of generating the allocation sequence (eg, computer-	N/A
3	ce		generated random numbers), and list of any factors for	
4	generati		stratification. To reduce predictability of a random sequence,	
5	on		details of any planned restriction (eg, blocking) should be	
6			provided in a separate document that is unavailable to those who	
7			enrol participants or assign interventions	
8				
9				
10	Allocatio	16b	Mechanism of implementing the allocation sequence (eg, central	N/A
11	n		telephone; sequentially numbered, opaque, sealed envelopes),	
12	conceal		describing any steps to conceal the sequence until interventions	
13	ment		are assigned	
14	mechani			
15	sm			
16				
17				
18	Implem	16c	Who will generate the allocation sequence, who will enrol	N/A
19	entation		participants, and who will assign participants to interventions	
20				
21	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial	N/A
22	(masking)		participants, care providers, outcome assessors, data analysts),	
23			and how	
24				
25				
26		17b	If blinded, circumstances under which unblinding is permissible,	N/A
27			and procedure for revealing a participant's allocated intervention	
28			during the trial	
29				

Methods: Data collection, management, and analysis

30				
31				
32	Data	18a	Plans for assessment and collection of outcome, baseline, and	Page 7
33	collection		other trial data, including any related processes to promote data	and fig
34	methods		quality (eg, duplicate measurements, training of assessors) and a	2
35			description of study instruments (eg, questionnaires, laboratory	
36			tests) along with their reliability and validity, if known. Reference	
37			to where data collection forms can be found, if not in the protocol	
38				
39				
40		18b	Plans to promote participant retention and complete follow-up,	N/A
41			including list of any outcome data to be collected for participants	
42			who discontinue or deviate from intervention protocols	
43				
44				
45	Data	19	Plans for data entry, coding, security, and storage, including any	8
46	managem		related processes to promote data quality (eg, double data entry;	
47	ent		range checks for data values). Reference to where details of data	
48			management procedures can be found, if not in the protocol	
49				
50				
51	Statistical	20a	Statistical methods for analysing primary and secondary	8
52	methods		outcomes. Reference to where other details of the statistical	
53			analysis plan can be found, if not in the protocol	
54				
55		20b	Methods for any additional analyses (eg, subgroup and adjusted	8
56			analyses)	
57				
58				
59				
60				

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
- 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

1				
2	Access to	29	Statement of who will have access to the final trial dataset, and	9
3	data		disclosure of contractual agreements that limit such access for	
4			investigators	
5				
6	Ancillary	30	Provisions, if any, for ancillary and post-trial care, and for	N/A
7	and post-		compensation to those who suffer harm from trial participation	
8	trial care			
9				
10	Disseminat	31a	Plans for investigators and sponsor to communicate trial results	9
11	ion policy		to participants, healthcare professionals, the public, and other	
12			relevant groups (eg, via publication, reporting in results	
13			databases, or other data sharing arrangements), including any	
14			publication restrictions	
15				
16				
17				
18		31b	Authorship eligibility guidelines and any intended use of	N/A
19			professional writers	
20				
21		31c	Plans, if any, for granting public access to the full protocol,	9
22			participant-level dataset, and statistical code	
23				
24				
25	Appendic			
26	es			
27	Informed	32	Model consent form and other related documentation given to	
28	consent		participants and authorised surrogates	
29	materials			
30				
31				
32	Biological	33	Plans for collection, laboratory evaluation, and storage of	N/A
33	specimens		biological specimens for genetic or molecular analysis in the	
34			current trial and for future use in ancillary studies, if applicable	
35				

*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" 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:	<i>BMJ Open</i>
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

SCHOLARONE™
Manuscripts

1
2
3
4
5 1 The Responding to Elder Abuse in GERiAtric care (REAGERA)
6
7 2 educational intervention for health care providers. A non-
8
9
10 3 randomised stepped wedge trial.
11
12 4

13
14 5 *Authors:*

15 6 Mikael Ludvigsson, MD, PhD ^{1,2}

17 7 Atbin Motamedi, MD ³

18 8 Björn Westerlind, MD, PhD ^{4,5}

19 9 Katarina Swahnberg, RN, PhD ⁶

20 10 Johanna Simmons, MD, PhD (corresponding author) ¹

21
22
23
24
25
26
27 11 *Affiliations:*

- 28
29 12 1. Department of Acute Internal Medicine and Geriatrics, and Department of Health, Medicine and
30
31 Caring Sciences, Linköping University, Linköping, Sweden.
32 13
33 14 2. Department of Psychiatry, and Department of Biomedical and Clinical Sciences, Linköping
34
35 University, Linköping, Sweden.
36 15
37 16 3. Department of Emergency Medicine in Norrköping, and Department of Health, Medicine and
38
39 Caring Sciences, Linköping University, Linköping, Sweden.
40 17
41 18 4. Department of Geriatrics, County Hospital Ryhov, Region Jönköping County, Jönköping, Sweden.
42
43 19 5. Department of Health, Medicine and Caring Sciences, Linköping University, Linköping, Sweden.
44
45 20 6. Department of Health and Caring Sciences, Faculty of Health and Life Sciences, Linnaeus
46
47 University, Kalmar, Sweden.

48
49
50
51
52
53
54
55
56 22 *Corresponding author*

57 23 Johanna Simmons

58 24 Postal address: Medicinska och geriatriska akutkliniken, Region Östergötland, 581 91 Linköping,
59
60 Sweden

Phone: +46 10 103 61 45

Fax: Not available

johanna.simmons@liu.se, johanna.r.simmons@gmail.com

30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56 30 *Key Words*

57 31 Elder abuse, Medical education, Forum Play, Forum Theatre

58
59
60 32 *Word count:* 4564

33 Abstract

34 *Introduction*

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

40 *Methods and analysis*

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

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

54 *Ethics and dissemination*

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

58 *Registration*

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

60 Strengths and limitations of this study

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

- 1
2
3 63 • The education tested is brief (one day), yet comprehensive, combining theory and group
4 discussions about elder abuse with interactive practical skills training, i.e. forum theatre.
5 64
6 65 • The education tested will be included in the ordinary continued educational programs at the
7 clinics participating in the study and all members of staff are anticipated to participate,
8 66 providing a sample that is generalizable to health care providers in geriatrics, internal
9 67 medicine, and primary care.
10 68
11 69 • One limitation of the study is that some important stakeholders are not included, e.g. health
12 care providers in surgical specialities and emergency medicine.
13 70
14 71 • The stepped wedge design provides an opportunity to assess if factors on the cluster level,
15 72 i.e. clinical level, impact the results.
16 73
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

74 Introduction

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

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

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

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

1
2
3 107 responsibility to care for victims; B) increase providers' perceived ability to ask questions about
4 108 abuse; C) increase providers perceived preparedness to manage cases of elder abuse; D) increase
5 109 organizational preparedness to care for older adults subjected to abuse.
6
7

8
9 110 The pedagogical framework underling the educational model is inspired by constructive alignment
10 111 theory, stating that learning objectives, learning activities and evaluation should be clearly aligned.
11 112 (21). Since the education is directed at professionals rather than students, no examination of the
12 113 acquired competence will be conducted, instead the evaluation constitutes the outcome measures
13 114 chosen to measure effectiveness of the model. As illustrated in figure 1, learning activities, i.e. a mix
14 115 of theoretical lectures, group discussions and forum theatre, were chosen to match the previously
15 116 stated learning objectives. Forum theatre is used as practical skills training and is a form of
16 117 interactive theatre where participants – together with drama pedagogues – practise dealing with
17 118 difficult situations and finding alternative ways of acting. Using interactive learning activities,
18 119 including practical training with simulated patients have previously been recommended when
19 120 educating about elder abuse (22-24). The forum theatre is expected to increase participants
20 121 confidence in managing difficult situations which in turn is expected to have a facilitating effect on
21 122 asking questions about abuse in future encounters. In both group discussions and forum theatre,
22 123 participants are encouraged to exchange ideas and share previous experiences, to make the
23 124 education relevant for their everyday practice. This is in line with constructive alignment theory,
24 125 which stipulate that learners actively construct their own knowledge based on e.g., previous
25 126 experiences, motives, assumptions and intentions (21). Also, to facilitate transferral of acquired
26 127 knowledge to practice we will give examples on how to formulate questions about abuse and provide
27 128 contact information to local support organizations. Previously, it has been highlighted that training
28 129 should be adapted to local conditions so that the education can easily be translated into everyday
29 130 practice (25). A pilot study evaluating the proposed educational model has been carried out
30 131 previously and the results of that study will be published separately (26).
31
32
33
34
35
36
37
38
39
40
41
42
43
44

45
46 132 [Insert figure 1 around here]
47

48 133 Aim

49 134 The overall aim of the project is to determine the effectiveness of an educational intervention on
50 135 health care providers' propensity to ask older patients questions about abusive experiences. More
51 136 specifically, we will:

- 52 137 1) Investigate whether the education increases propensity to ask questions about abuse.
- 53 138 2) Investigate whether the education affects participants' perceived barriers to asking
- 54 139 questions, i.e. a) awareness and sense of responsibility to care for victims of abuse b)

1
2
3 140 perceived ability to ask questions about abuse c) perceived preparedness to manage cases of
4
5 141 elder abuse and d) perceived preparedness at the clinic to care for older adults subjected to
6
7 142 abuse.

143 Method and analysis

144 *Design*

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

156
157 [Insert Figure 2 around here]

158
159 The intervention will be rolled out during four periods between September 2021 and spring 2023
160 (figure 2). A complete stepped wedge design would therefore entail at least five measurement
161 points, which was deemed to be a too heavy response burden. Therefore, an incomplete design was
162 chosen, i.e., six periods are used, but every cluster is only included at four measurement points: at
163 baseline, in conjunction with the education, at six months follow up and at twelve months follow up.
164 The times of data collection is illustrated in figure 1. Similar incomplete designs have been described
165 previously (28, 29). For practical reasons the primary care centres included in the first study period
166 had to be included later than the hospital clinics, i.e., in December 2021. To avoid a data collection
167 period during the summer vacation, their first follow up will be in late august, i.e., eight months post
168 intervention. Thereafter they will fall into the same pattern of data collection at six months interval
169 as the other clinics. The six month interval was chosen because it provides an intermediate (six
170 months) and long-term (twelve months) follow up that allows for a reasonable evaluation of the
171 effect of the education. Ideally in a stepped wedge trial, the included clusters are randomised to
172 when they will make the transition from control group to intervention group. However, considering

1
2
3 173 that all staff at each participating clinic or unit will undergo a full-day training session, this requires a
4 174 lot of planning on the part of the participating clinics. It was therefore not possible to carry out
5 175 randomisation, but instead the clinics were slotted into the schedule in the stages that were best
6 176 suited to the schedules of their own organisations.

10 177 *Participants*

11 178 Staff at six in-patient care units within internal medicine and geriatrics at four of the six hospitals in
12 179 two regions (Region Östergötland and Region Jönköpings Län) in Sweden, as well as three of the 45
13 180 primary care centres in Region Östergötland will be invited to participate in a full-day education
14 181 concerning elder abuse. The education is included in the clinics continuing education program and as
15 182 far as possible (considering clinical responsibilities) all staff, e.g., nurses, assistant nurses, physicians,
16 183 occupational and physical therapists, will be scheduled to take part in the education. All staff
17 184 participating will be asked for inclusion in the study but agreeing is not a prerequisite to partake in
18 185 the education. Staff who are not engaged in clinical work with older patients (age 65 and older) will
19 186 be excluded from the study but welcome to participate in the education. Approximately 750 health
20 187 care providers will be asked to participate. The number is estimated based on the known number of
21 188 participants in the educations during the first period of data collection (fall 2021) and the anticipated
22 189 number of participants in the forthcoming educations, as provided by management at the
23 190 participating clinics (figure 2).

24 191 The sample of units was based on convenience, i.e. the clinics were recruited with the help of
25 192 personal connections members of the research team had. The researchers are however not generally
26 193 known to the health care providers participating in the study, with two notable exceptions: 1) Two of
27 194 the researchers (JS and ML) – who are also responsible for delivering the education – are employed
28 195 at the clinic that first underwent the education; 2) One other researcher (BW) is employed at one of
29 196 the other geriatric clinics included. He does however not have an active role in delivering the
30 197 education.

33 198 *Learning activities – Content of the educational intervention*

34 199 The different learning activities used during the education and their alignment with the learning
35 200 objectives and evaluation is illustrated in figure 1.

36 201 *Theoretical training (lectures and group discussions)*

37 202 During the first part of the educational day, two members of the research group (JS and ML) give
38 203 lectures interspersed with group discussions. Three themes are covered:

39 204 1) **What is elder abuse?** The education starts by showing a short film portraying a woman subjected
40 205 to abuse by her partner. The film is shown to illustrate the complexity of elder abuse and to elicit

1
2
3 206 emotions. In the associated lecture the definition of elder abuse, prevalence, risk factors and health
4
5 207 consequences of elder abuse are presented. Group discussions focus on what constitutes elder abuse
6
7 208 as well as participants' own experiences of meeting patients subjected to abuse.

8
9 209 **2) How can I ask questions about abuse?** We present regulations from the Swedish National Board
10
11 210 of Health and Welfare stating that health care providers should ask questions about abuse whenever
12
13 211 there are signs or symptoms that may indicate abuse (30). Symptoms that may be associated with
14
15 212 abuse are discussed but we emphasise that there are no pathognomonic signs and that questions
16
17 213 often need to be asked regardless of indicators of abuse. The self-administered questionnaire
18
19 214 REAGERA-S (31) is introduced as a tool for asking older adults about experiences of abuse. Associated
20
21 215 group discussions focus on how to ask questions about abuse, and we allow some time to practice
22
23 216 using the REAGERA-S.

24
25 217 **3) An older patient told me about abuse – how do I handle the situation?** There is no evidence-
26
27 218 based practice on how to best manage cases of elder abuse (32, 33). Instead, interventions against
28
29 219 elder abuse must be individually tailored to match the unique needs and preferences of the older
30
31 220 adult (34). We introduce trauma-informed care as a concept, meaning e.g., being aware of trauma
32
33 221 symptoms, working to prevent re-traumatization in health care and emphasising survivors' voice and
34
35 222 empowerment in the care provided (35, 36). We also present local resources for victims and regional
36
37 223 guidelines about managing cases of elder abuse. Group discussions focuses on how to handle the
38
39 224 situation when an older patient discloses abusive experiences.

40
41 225 Short films that show patient-provider encounters are used to introduce group discussions during
42
43 226 theme two and three. Two versions of each patient-provider encounter have been filmed to show
44
45 227 that the encounter develops differently depending on how staff act. One pair of films are about
46
47 228 asking questions about abuse (theme 2) and one set of films are about responding when a patient
48
49 229 discloses abusive experiences (theme 3). After viewing each film, the content is discussed in small
50
51 230 groups: What went well in the encounter, what went less well and how can it been done differently?

52 231 *Forum theatre*

53
54 232 The second part of the educational day is devoted to forum theatre, a form of interactive theatre
55
56 233 (37) led by three drama pedagogues. Before starting, the participants form small groups to work out
57
58 234 case descriptions of care situations pertaining to elder abuse that they themselves have perceived as
59
60 235 challenging to deal with. Two pre-prepared and rehearsed patient cases based on research and
61
62 236 clinical experience of difficult encounters with victims of elder abuse are also used. The forum
63
64 237 theatre starts with the drama pedagogues acting out a provider-patient encounter where something
65
66 238 went wrong or was difficult to manage. The scene is then acted out a second time, but this time the

1
2
3 239 participants are invited to intervene in the encounter by saying “stop” when the sequence of events
4
5 240 is heading in a dysfunctional direction. The participant saying stop then takes over the role of the
6
7 241 drama pedagogue acting as the health care provider and tries another way of managing the situation
8
9 242 played out in the scene. Alternatively, the participant instructs the drama pedagogue how to act
10
11 243 differently. Thus the participants and the drama pedagogues together explore how their ways of
12
13 244 acting can influence and improve a difficult encounter. While working with the scene, participants
14
15 245 and drama pedagogues also engage in discussions about what is happening, the difficulties
16
17 246 encountered and potential solutions. After each scene has been worked through, a brief remark is
18
19 247 given by JS or ML regarding how to provide help in the specific case. This provides participants with
20
21 248 some model cases that they can later relate to when faced with similar situations. Previously, forum
22
23 249 theatre has been described as an innovative training model that stimulates reflection and learning
24
25 250 within the health care system (38).

24 251 *Post-training reflection on changing practices*

25
26 252 To facilitate transferral of the newly gained knowledge to participants’ everyday practice, the
27
28 253 educational day ends with a discussion on how to move forward. How can the training and the tools
29
30 254 provided during the education be incorporated into clinical routines? This is first discussed in small
31
32 255 groups and then further elaborated on with all participants, with the intention to stimulate thoughts
33
34 256 and plans about how preparedness to care for victims can be improved at the clinic.

35 257 **Material and analysis**

36
37 258 Data will be collected with the REAGERA-P (Responding to Elder Abuse in GERiatric care – Provider
38
39 259 questionnaire). It is a validated instrument (39) that can be used to measure health care providers’
40
41 260 preparedness to ask older patients questions about abuse and manage the response. The items of
42
43 261 relevance for this study are presented in table 1 and the complete REAGERA-P as supplementary file
44
45 262 1.

46 263 [insert Table 1 around here]

47
48
49 264 Construct and convergent validity of the REAGERA-P was previously tested in a sample of 154 health
50
51 265 care providers by using factor analysis, test of internal consistency and by investigating associations
52
53 266 between relevant variables (39). Based on lessons learned in that data collection the instrument was
54
55 267 further improved and has later been used to evaluate a pilot study of the current educational
56
57 268 intervention (26). In the pilot study, a possible ceiling effect was found for two items about sense of
58
59 269 responsibility and therefore the response categories were modified for the current study, i.e.,
60
270 changed from a four-point ordinal scale to a six-point ordinal scale. Also, to better capture change in
271
271 frequency of asking questions about abuse, response categories for the main outcome measure

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

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

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

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

295 *Statistical analyses*

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

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

1
2
3 304 questions about abuse) in all clusters pre-intervention with all clusters post-intervention. Both mean
4
5 305 difference in reported frequency of asking questions and changes in proportion of participants that
6
7 306 report ever having asked questions about abuse will be reported. For the continuous outcome a
8
9 307 linear mixed effect model will be used and for the binary outcome a generalised linear mixed effect
10
11 308 model. The models will consider repeated measures and include cluster as random effect to
12
13 309 determine if the anticipated effect of the model is dependent on the cluster, i.e. unit or clinic. During
14
15 310 a stepped wedge trial more and more clusters will gradually transition from unexposed to exposed
16
17 311 status, meaning that observation in the exposed status will on average be of a later date than the
18
19 312 unexposed observation (40). This may introduce a bias in the study considering that there may be
20
21 313 underlying temporal trends affecting the outcome, e.g. an increasing awareness of elder abuse in
22
23 314 society over time. Therefore, both intervention status and time will be included as fixed effects in the
24
25 315 models. Also, models will be adjusted for covariates, e.g. background characteristics, significantly
26
27 316 associated with the outcome.

28
29 317 As previously described, we propose that the education will work by participants overcoming
30
31 318 personal and organizational barriers towards asking older patients questions about abuse. The items
32
33 319 in REAGERA-P used to evaluate the effect on the different barriers and facilitators are described in
34
35 320 figure 1 and they will be included in linear models (for continuous outcome) and generalised linear
36
37 321 models (for binary outcomes) to determine the effect of the intervention on these outcomes. If
38
39 322 results support the theoretical model, efforts will be made to test if changes in perceived barriers
40
41 323 mediate a potential effect of the intervention on the primary outcome, i.e. asking questions about
42
43 324 abuse.

44
45 325 Data from the medical records will be retrieved for the following periods a) 6 months pre-
46
47 326 intervention, b) 0-6 months post intervention and c) 6-12 months post intervention. A linear mixed
48
49 327 effect model will be used to investigate changes concerning how many victims are identified pre- and
50
51 328 post-intervention at the participating clinics.

52
53 329 In all models, we will strive for parsimony; analysis will therefore be performed to determine which
54
55 330 variables to include in multivariate analysis and only covariates that significantly affect the model will
56
57 331 be included. Assumptions for models will be assessed graphically and, if needed, bootstrapping will
58
59 332 be used to ensure model robustness. Significance level will be set at $p=0.05$ and results will be
60
61 333 reported with 95% confidence intervals.

334 *Sample size calculation*

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

1
2
3 337 calculations conducted by the web application is presented elsewhere (41), as well as on the website.
4
5 338 The significance level was set at 0.05 and power at 0.8. Initially we had planned a complete four
6
7 339 period stepped wedge design and hence, that was used in the sample size calculation together with
8
9 340 the discrete time decay. Divergent cluster sizes were expected and coefficient of variation for a
10
11 341 cluster size was set at 0.5. Results from the pilot study was used to estimate cluster auto correlation
12
13 342 at 0.6. Proportion was set as outcome, and we used data from the pilot study to estimate the
14
15 343 proportion under control at 0.26 and the proportion under intervention at 0.56. An illustration of the
16
17 344 trade-off between cluster size and number of clusters per arm calculated can be found in as
18
19 345 supplementary file 2. The illustration also includes the parameters used in calculation and show that
20
21 346 a cluster size of 10 sufficed to reach adequate power. Since our smallest expected cluster has 31
22
23 347 participants, even a response rate of less than 40% is sufficient.

348 *Patient and public involvement*

24 349 A pilot study of the education was conducted in 2020, and qualitative interviews were subsequently
25
26 350 conducted with some participants to ensure that the education was relevant to their practice (26).
27
28 351 This led to changes in the education that are implemented at this stage, e.g., a stronger focus on how
29
30 352 to manage cases and providing information about local societal resources available to victims.
31
32 353 Cognitive interviews with health care providers were also used as one of the measures to validate
33
34 354 the questionnaire used to evaluate the intervention (REAGERA-P) (39). This was done to ensure the
35
36 355 comprehensibility of the questions, and also to make sure that the questions used for evaluation are
37
38 356 perceived as relevant. There was no patient involvement when constructing the intervention.
39
40 357 However, the research group has previously conducted qualitative studies with older patients
41
42 358 subjected to abuse (34) and the results of those interviews have inspired the content of the
43
44 359 intervention.

360 *Ethics and dissemination*

45 361 The study has been approved by the Swedish Ethical Review Authority (reference no. 2020-02548).
46
47 362 Informed consent (Supplementary file 3) is obtained as the first part of REAGERA-P and must be
48
49 363 given before starting to fill out the questionnaire at all data collection points. The database will be
50
51 364 securely stored by Region Östergötland and only authorised persons will have access to the data. The
52
53 365 results of the study will be published in peer-reviewed journals and conference proceedings.
54
55 366 Anonymous data will be made available by the primary investigator upon reasonable request after
56
57 367 results have been published. As a final product of the study, a manual of the course content will be
58
59 368 published. The purpose is to use this manual to disseminate the course to other clinics or
60
369 organisations that wish to use it.

370 Discussion

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

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

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

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

1
2
3 403 needed considering how effective response systems can be constructed and how elder abuse can be
4
5 404 prevented (32, 35, 42, 43).
6
7

8 405 Contributorship statement

9
10 406 The study concept was conceived by JS who is also the primary investigator. JS, ML, KS and AM
11 407 planned the content of the educational intervention. JS, ML, KS and BW planned the study design
12 408 and data collection. JS is responsible for data collection and AM will conduct data analysis assisted by
13 409 JS, ML, KS and a statistician. JS wrote the first draft of the manuscript and ML, KS, BW and AM
14 410 performed critical revisions for important intellectual content. JS, ML, BW, KS, AM all read and
15 411 approved the final manuscript.
16
17
18
19
20

21 412 Conflicts of interests

22 413 The authors have no competing interests to declare.
23
24

25 414 Funding

26
27 415 This study is mainly funded by internal sources at Region Östergötland (no specific award/grant).
28 416 Also, funding has been granted by the Kamprad family foundation (grant no 20210151). Funders
29 417 have had no role in study design and will not have any role in data collection, management, analysis,
30 418 interpretation of data, writing report or decision to submit the reports.
31
32
33
34

35 419 Data sharing statement

36 420 There is no data supporting this study protocol. When the data collection has been completed and
37 421 reports are published, anonymous data will be made available by the primary investigator (JS) upon
38 422 reasonable request.
39
40
41
42

43 423 Acknowledgement

44 424 The authors wish to acknowledge Karolin Olstam for her important help in producing the short films
45 425 used to introduce the group discussion under theme two and three in the theoretical part of the
46 426 education.
47
48
49

50 427 References

- 51
52 428 1. Yon Y, Mikton CR, Gassoumis ZD, Wilber KH. Elder abuse prevalence in community
53 429 settings: a systematic review and meta-analysis. *The Lancet Global Health*. 2017;5(2):e147-e56.
54
55 430 2. Pillemer K, Burnes D, Riffin C, Lachs MS. Elder Abuse: Global Situation, Risk Factors,
56 431 and Prevention Strategies. *The Gerontologist*. 2016;56(Suppl_2):S194-S205.
57
58
59
60

- 3 432 3. Yon Y, Ramiro-Gonzalez M, Mikton CR, Huber M, Sethi D. The prevalence of elder
4 433 abuse in institutional settings: a systematic review and meta-analysis. *European Journal of Public*
5 434 *Health*. 2018;29(1):58-67.
- 8 435 4. WHO. The Toronto Declaration on the Global Prevention of Elder Abuse. 2002.
- 9 436 5. Storey JE. Risk factors for elder abuse and neglect: A review of the literature. *Aggress*
10 437 *Violent Beh*. 2020;50:101339.
- 13 438 6. Dong X, Simon MA. Elder abuse as a risk factor for hospitalization in older persons.
14 439 *JAMA internal medicine*. 2013;173(10):911-7.
- 16 440 7. Dong XQ. Elder Abuse: Systematic Review and Implications for Practice. *Journal of the*
17 441 *American Geriatrics Society*. 2015;63(6):1214-38.
- 20 442 8. Burnes D, Acierno R, Hernandez-Tejada M. Help-Seeking Among Victims of Elder
21 443 Abuse: Findings From the National Elder Mistreatment Study. *J Gerontol B Psychol Sci Soc Sci*.
22 444 2019;74(5):891-6.
- 25 445 9. Lachs MS, Pillemer KA. Elder Abuse. *The New England journal of medicine*.
26 446 2015;373(20):1947-56.
- 28 447 10. Dow B, Gahan L, Gaffy E, Joosten M, Vrantsidis F, Jarred M. Barriers to Disclosing Elder
29 448 Abuse and Taking Action in Australia. *J Fam Violence*. 2020;35(8):853-61.
- 31 449 11. Fraga Dominguez S, Storey JE, Glorney E. Help-Seeking Behavior in Victims of Elder
32 450 Abuse: A Systematic Review. *Trauma Violence Abuse*. 2021;22(3):466-80.
- 35 451 12. Socialdepartementet. Nationell strategi om våld mot äldre personer inom vård och
36 452 omsorg, Bilaga till protokoll vid regeringssammanträde 2014-06-12 nr II:15 2014.
- 38 453 13. Simmons J, Swahnberg K. Characteristics Associated With Being Asked About Violence
39 454 Victimization in Health Care: A Swedish Random Population Study. *Journal of Interpersonal Violence*.
40 455 2020;0(0):0886260520977836.
- 43 456 14. Touza Garma C. Influence of health personnel's attitudes and knowledge in the
44 457 detection and reporting of elder abuse: An exploratory systematic review. *Psychosocial Intervention*.
45 458 2017;26(2):73-91.
- 48 459 15. Schmeidel AN, Daly JM, Rosenbaum ME, Schmuck GA, Jogerst GJ. Healthcare
49 460 Professionals' Perspectives on Barriers to Elder Abuse Detection and Reporting in Primary Care
50 461 Settings. *Journal of elder abuse & neglect*. 2012;24(1):17-36.
- 53 462 16. Mohd Mydin FH, Othman S. Elder Abuse and Neglect Intervention in the Clinical
54 463 Setting: Perceptions and Barriers Faced by Primary Care Physicians in Malaysia. *J Interpers Violence*.
55 464 2020;35(23-24):6041-66.

- 1
2
3 465 17. Cooper C, Selwood A, Livingston G. Knowledge, detection, and reporting of abuse by
4 466 health and social care professionals: a systematic review. *The American journal of geriatric psychiatry*
5 467 : official journal of the American Association for Geriatric Psychiatry. 2009;17(10):826-38.
- 6
7
8 468 18. Brijnath B, Gahan L, Gaffy E, Dow B. "Build Rapport, Otherwise No Screening Tools in
9 469 the World Are Going to Help": Frontline Service Providers' Views on Current Screening Tools for Elder
10 470 Abuse. 2018.
- 11
12
13 471 19. Motamedi A, Ludvigsson M, Simmons J. Factors associated with health care providers
14 472 speaking with older patients about being subjected to abuse. *Journal of elder abuse & neglect*.
15 473 2022;34(1):20-37.
- 16
17
18 474 20. Hoover RM, Polson M. Detecting elder abuse and neglect: assessment and
19 475 intervention. *Am Fam Physician*. 2014;89(6):453-60.
- 20
21
22 476 21. Biggs J. Enhancing teaching through constructive alignment. *Higher Education*.
23 477 1996;32(3):347-64.
- 24
25 478 22. Mohd Mydin FH, Yuen CW, Othman S. The Effectiveness of Educational Intervention in
26 479 Improving Primary Health-Care Service Providers' Knowledge, Identification, and Management of
27 480 Elder Abuse and Neglect: A Systematic Review. *Trauma, Violence, & Abuse*.
28 481 2019:1524838019889359.
- 29
30
31 482 23. Pickering CEZ, Ridenour K, Salaysay Z, Reyes-Gastelum D, Pierce SJ. EATI Island – A
32 483 virtual-reality-based elder abuse and neglect educational intervention. *Gerontology & Geriatrics*
33 484 *Education*. 2018;39(4):445-63.
- 34
35
36 485 24. Fisher JM, Rudd MP, Walker RW, Stewart J. Training Tomorrow's Doctors to Safeguard
37 486 the Patients of Today: Using Medical Student Simulation Training to Explore Barriers to Recognition
38 487 of Elder Abuse. *Journal of the American Geriatrics Society*. 2016;64(1):168-73.
- 39
40
41 488 25. Alt KL, Nguyen AL, Meurer LN. The Effectiveness of Educational Programs to Improve
42 489 Recognition and Reporting of Elder Abuse and Neglect: A Systematic Review of the Literature. *Journal*
43 490 *of elder abuse & neglect*. 2011;23(3):213-33.
- 44
45
46 491 26. Simmons J, Motamedi A, Ludvigsson M, Swahnberg K. Testing an educational
47 492 intervention to improve health care providers' preparedness to care for victims of elder abuse. A
48 493 mixed method pilot study. *Research Square [Preprint]*. 2022. [Accessed 2022 April 2]. DOI:
49 494 10.21203/rs.3.rs-1510390/v1.
- 50
51
52 495 27. Brown CA, Lilford RJ. The stepped wedge trial design: a systematic review. *BMC*
53 496 *Medical Research Methodology*. 2006;6(1):54.
- 54
55
56 497 28. Copas AJ, Lewis JJ, Thompson JA, Davey C, Baio G, Hargreaves JR. Designing a stepped
57 498 wedge trial: three main designs, carry-over effects and randomisation approaches. *Trials*.
58 499 2015;16(1):352.

- 1
2
3 500 29. Hemming K, Lilford R, Girling AJ. Stepped-wedge cluster randomised controlled trials: a
4 501 generic framework including parallel and multiple-level designs. *Statistics in Medicine*.
5 502 2015;34(2):181-96.
6
7
8 503 30. Swedish National Board of Health and Welfare. *Våld i Nära relationer, SOSFS 2014:4*.
9 504 Stockholm; 2014.
10
11 505 31. Simmons J, Wiklund N, Ludvigsson M, Nägga K, Swahnberg K. Validation of REAGERA-
12 506 S: a new self-administered instrument to identify elder abuse and lifetime experiences of abuse in
13 507 hospitalized older adults. *Journal of elder abuse & neglect*. 2020;32(2):173-95.
14
15
16 508 32. Fearing G, Sheppard CL, McDonald L, Beaulieu M, Hitzig SL. A systematic review on
17 509 community-based interventions for elder abuse and neglect. *Journal of elder abuse & neglect*.
18 510 2017;29(2-3):102-33.
19
20
21 511 33. Baker PR, Francis DP, Mohd Hairi NN, Othman S, Choo WY. Interventions for
22 512 preventing elder abuse: applying findings of a new Cochrane review. *Age and ageing*. 2016;46(3):346-
23 513 8.
24
25
26 514 34. Ludvigsson M, Wiklund N, Swahnberg K, Simmons J. Experiences of elder abuse: a
27 515 qualitative study among victims in Sweden. *BMC Geriatrics*. 2022;22(1):256.
28
29
30 516 35. Ernst JS, Maschi T. Trauma-informed care and elder abuse: a synergistic alliance.
31 517 *Journal of elder abuse & neglect*. 2018;30(5):354-67.
32
33
34 518 36. SAMHSA. Trauma-informed care in behavioral health services. Treatment
35 519 Improvement Protocol (TIP) Series 57. Rockville, MD. : US Department of Health Human Services;
36 520 2014. Contract No.: HHS Publication No (SMA) 14-4816.
37
38 521 37. Boal A. *Theatre of the oppressed*. London: Pluto Press; 2000.
39
40 522 38. Bruggemann AJ, Persson A. Using forum play to prevent abuse in health care
41 523 organizations: A qualitative study exploring potentials and limitations for learning. *Education for*
42 524 *health (Abingdon, England)*. 2016;29(3):217-22.
43
44
45 525 39. Simmons J, Wenemark M, Ludvigsson M. Development and validation of REAGERA-P, a
46 526 new questionnaire to evaluate health care provider preparedness to identify and manage elder
47 527 abuse. *BMC Health Serv Res*. 2021;21(1):473.
48
49
50 528 40. Hemming K, Haines TP, Chilton PJ, Girling AJ, Lilford RJ. The stepped wedge cluster
51 529 randomised trial: rationale, design, analysis, and reporting. *BMJ : British Medical Journal*.
52 530 2015;350:h391.
53
54
55 531 41. Hemming K, Kasza J, Hooper R, Forbes A, Taljaard M. A tutorial on sample size
56 532 calculation for multiple-period cluster randomized parallel, cross-over and stepped-wedge trials
57 533 using the Shiny CRT Calculator. *International Journal of Epidemiology*. 2020;49(3):979-95.
58
59
60

1
2
3 534 42. Baker PRA, Francis DP, Hairi NN, Othman S, Choo WY. Interventions for preventing
4 535 abuse in the elderly. Cochrane Database of Systematic Reviews. 2016(8).

5 536 43. Storey JE, Perka MR. Reaching Out for Help: Recommendations for Practice Based on
6 537 an In-Depth Analysis of an Elder Abuse Intervention Programme. The British Journal of Social Work.
7 538 2018;48(4):1052-70.

8
9
10
11
12 539

13
14
15 540
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

1
2
3
4 541 **Figure legends**

5
6 542 **Figure 1. Theoretical model.** An illustration of the alignment between learning activities (yellow),
7 543 learning objective, i.e., barriers and facilitators on a personal (green) and organizational (blue) level
8 544 as well as evaluation (red).

9
10
11 545 **Figure 2. Design of the study and data collection points.** An incomplete stepped wedge trial is
12 546 planned. All clusters are measured pre-intervention (yellow squares = baseline and in conjunction
13 547 with the educational day) and post-intervention (blue squares = at 6-8 months and 12-14 months
14 548 follow up). Time of intervention is denoted by the red contour.

15
16
17
18
19 549
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

550 **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	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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.)	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Not at all concerned • A little concerned • Somewhat concerned • Very concerned

551

552

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.)	<ul style="list-style-type: none"> • 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? <ul style="list-style-type: none"> • That I will not be able to offer the patient a good follow-up 	<ul style="list-style-type: none"> • 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?	<ul style="list-style-type: none"> • 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?	<ul style="list-style-type: none"> • 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?	<ul style="list-style-type: none"> • 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? <ul style="list-style-type: none"> • Deficient routines at the workplace for asking questions • Deficient routines at the workplace for handling the answer. 	<ul style="list-style-type: none"> • 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?	<ul style="list-style-type: none"> • Very good • Fairly good • Somewhat inadequate • Very inadequate • Don't know what preparedness there is

553

554

555

2021-060314 on 04 March 2022. Downloaded from <http://bmjopen.bmj.com/> on April 20, 2024 by guest. Protected by copyright.

1
2
3
4
5
6
7
8
9
10
11
12
13

Learning activities

- Theoretical theme 1 (What is elder abuse?)
 - Short films and group discussions
 - Building on own experiences
 - Forum theatre (eliciting emotions)
- Theoretical theme 2 (How can I ask questions about abuse?)
 - Short films and group discussions
 - Building on own experiences
 - Forum theatre (skills training)
- Theoretical themes 3 (An older patient told me about abuse – how do I handle the situation?)
 - Presenting regional guidelines
 - Providing contact information to local services for victims
 - Short films and group discussions
 - Building on own experiences
 - Forum theatre (skills training)
- Post-training reflection
 - Whole clinic participating
 - Presenting regional guidelines

14
15
16
17
18
19
20
21
22

Learning objectives
(decreasing barriers, increasing facilitators)

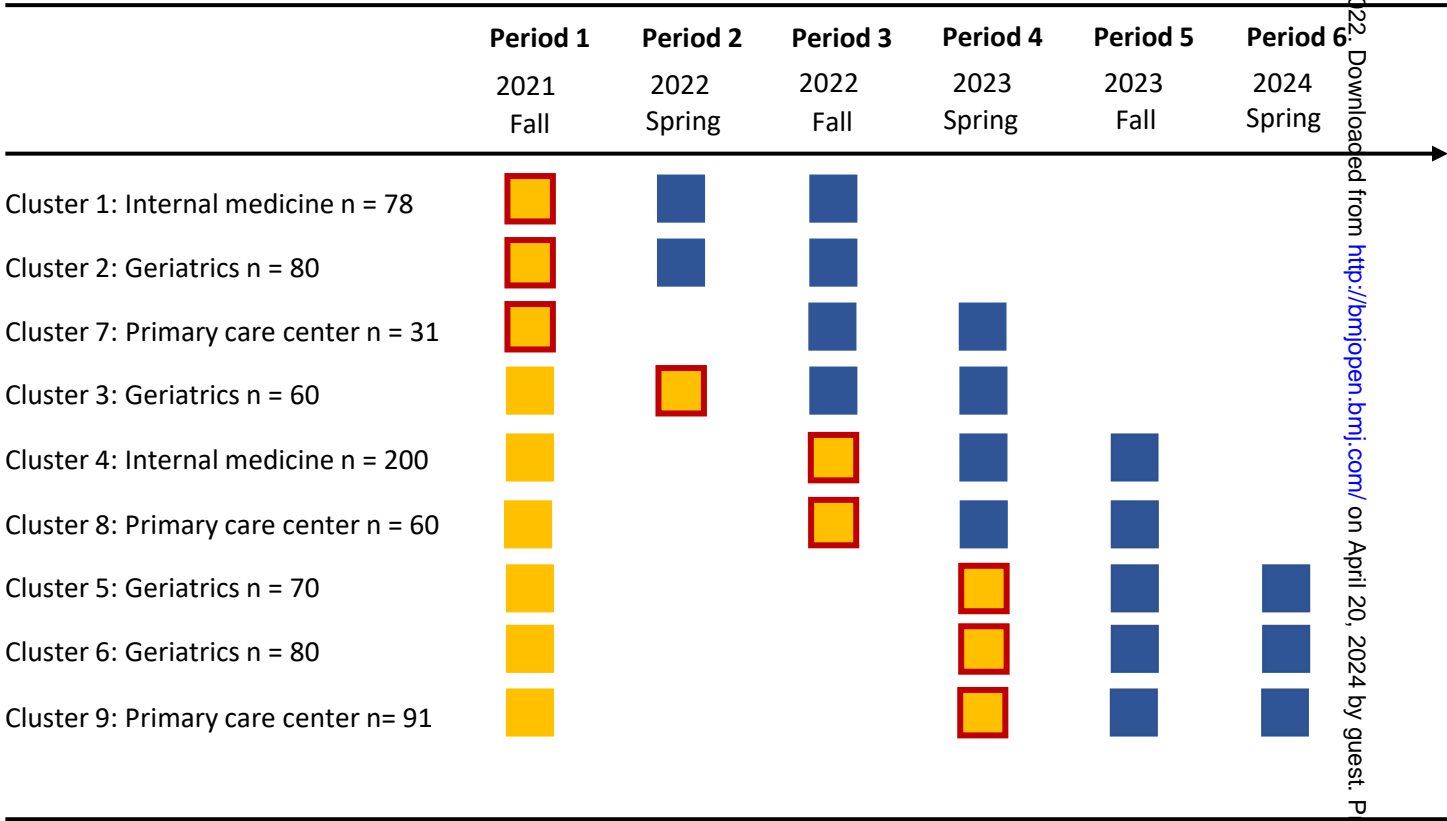
- Awareness of EA**
 - Sense of responsibility for identifying victims**
- Perceived ability to ask questions about abuse**
- Preparedness to manage cases of elder abuse**
- Preparedness at the clinic to care for older adults subjected to abuse**

23
24
25
26
27
28
29
30
31
32
33
34
35
36

Evaluation
(i.e., items in REAGERA-P used to evaluate the learning objectives)

- Lack of awareness
 - Own responsibility
 - Own profession's responsibility
 - Health care responsibility
 - Case vignette
- Self-efficacy for asking questions
 - Concern about effect on relationship
 - Concern about negative patient reaction
- Self-efficacy for managing the response
 - Concern about not being able to give proper follow-up
 - Know which colleague to ask for advice
 - Knowledge about proper documentation routines
 - Knowledge about judicial concerns
- Clinical routines for asking questions
 - Clinical routines for managing the response
 - Preparedness at the clinic

Asking questions about abuse



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

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
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 a primary 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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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 manage it very poorly					Would manage it very well					
	0	1	2	3	4	5	6	7	8	9	10
a. Asking questions about abuse to an older patient who has clear indications of now being, or having previously been, subjected to abuse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Asking questions about abuse to an older patient who has no clear indications of now being or having previously been, subjected to abuse.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. In conversation, providing support to an older patient who tells about abuse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Helping an older patient subjected to abuse on to the right body in healthcare, or to the right support function in society	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Helping an older patient subjected to abuse to make a report to the police or social services	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Helping and supporting an older patient subjected to abuse, who does not currently want to change his or her situation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

1
2
3 **25. Approximately how many times did the questions lead to an older patient telling about abuse**
4 **that he or she experienced?**

- 5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
- None
 - None
 - 1 time
 - 2 times
 - 3 times
 - 4 times
 - 5 times
 - 6 times
 - 7 times
 - 8 times
 - 9 times
 - 10 times or more

20
21 **26. Have you at any time had lingering suspicions that the patient is or has been subjected to abuse**
22 **even though he or she has denied it when you asked questions about it?**

- 23
24
25
26
- No
 - Yes, once
 - Yes, several times

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

28
29
30 **28. Think about the last time an older patient told you about abuse. *To what extent do you think***
31 ***that the patient received a good follow-up?***

- 32
33
34
35
36
37
38
39
40
41
42
- 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

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

44
45
46 **30. In the past six months, have you had suspicions that an older patient was subjected to abuse,**
47 **but did not ask questions about it?**

- 48
49
50
51
52
53
54
55
56
57
58
59
60
- 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Assistant nurse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Counsellor and psychologist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Physician	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other professions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

1
2
3
4 **40. Inadequate routines at the workplace for asking questions**

- 5
6
7
8
9
10
11
12
- Not at all
 - To a small extent
 - To some extent
 - To a somewhat large extent
 - To a large extent
 - To a very large extent

13
14 **41. Inadequate routines at the workplace for handling the answer**

- 15
16
17
18
19
20
21
22
- Not at all
 - To a small extent
 - To some extent
 - To a somewhat large extent
 - To a large extent
 - To a very large extent

23
24 **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?**

- 25
26
27
28
- Yes
 - No

29
30 **43. How do you think the preparedness at your workplace is for taking care of older patients subjected to abuse?**

- 31
32
33
34
35
36
37
- Very good
 - Fairly good
 - Somewhat inadequate
 - Very inadequate
 - Don't know what preparedness there is

38
39
40 **44. How do you think the preparedness in society is for taking care of older patients subjected to abuse?**

- 41
42
43
44
45
46
47
- Very good
 - Fairly good
 - Somewhat inadequate
 - Very inadequate
 - Don't know what preparedness there is

48
49
50 **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?**

- 51
52
53
54
55
56
57
58
59
60
- Absolutely
 - To a large extent
 - To some extent
 - Not really

1
2
3 **46. Do you think you have enough legal knowledge, for example about when and to whom one**
4 **can/must report if an older patient is mistreated and what secrecy rules apply?**

- 5
6
7
8
9
10
- Absolutely
 - To a large extent
 - To some extent
 - Not really

11
12 **I. Own exposure to violence**

13 Below are some concluding questions of a more personal nature. They are about your own possible
14 experiences of having been subjected to abuse in life. We are asking the questions to be able to
15 investigate if there is an association between what one has personally experienced in life and how one
16 relates to older patients who have been subjected to abuse. As for other questions in the questionnaire,
17 your responses are personal, but all analyses are done on a group level and that is also how the results
18 will be presented.
19

20
21 It is common to have been subjected to some kind of abuse during life. If this is your case and you have a
22 need for support and help to process this, please turn to one of the support services that are described
23 in the folder you received in connection with the training day. [Alternative text control group: ...in the
24 folder you received in connection with the invitation to participate in the study.]
25

26
27 If you do not want to answer these questions, you may opt to pass by them one by one.
28

29 **47. Have you yourself, as a child or as an adult, been subjected to any kind of physical abuse?**

30 Such as being beaten, kicked, forcibly held or subjected to other physical violence that you perceived as
31 frightening

- 32
33
34
35
- No
 - Yes, as a child (<18 years)
 - Yes, as an adult (≥18 years)

36
37 **47b. Who subjected you to abuse as an adult (≥18 years)?**

- 38
39
40
41
42
- A partner or former partner
 - A family member or relative
 - Another person I knew
 - A completely unknown person

43
44 **47c. Who subjected you to abuse as a child (<18 years)?**

- 45
46
47
48
49
- A partner or former partner
 - A family member or relative
 - Another person I knew
 - A completely unknown person

50
51 **48. Have you yourself, as a child or as an adult, been subjected to any kind of sexual abuse?**

52 Such as somebody touching your body against your will or forcing you to perform sexual acts

- 53
54
55
56
- No
 - Yes, as a child (<18 years)
 - Yes, as an adult (≥18 years)

1
2
3
4 **48b. Who subjected you to abuse as an adult (≥ 18 years)?**

- 5
6
7
8
9
10
- A partner or former partner
 - A family member or relative
 - Another person I knew
 - A completely unknown person

11 **48c. Who subjected you to abuse as a child (< 18 years)?**

- 12
13
14
15
16
17
- A partner or former partner
 - A family member or relative
 - Another person I knew
 - A completely unknown person

18 **49. Have you yourself, as a child or as an adult, been subjected to any kind of emotional abuse?**

19 For example, that somebody repeatedly degraded you, humiliated you or tried to limit your contact
20 with others or decide what you may and may not do

- 21
22
23
24
25
- No
 - Yes, as a child (< 18 years)
 - Yes, as an adult (≥ 18 years)

26 **49b. Who subjected you to abuse as an adult (≥ 18 years)?**

- 27
28
29
30
31
32
- A partner or former partner
 - A family member or relative
 - Another person I knew
 - A completely unknown person

33 **49c. Who subjected you to abuse as a child (< 18 years)?**

- 34
35
36
37
38
39
- A partner or former partner
 - A family member or relative
 - Another person I knew
 - A completely unknown person

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

- 43
44
45
46
47
- No
 - Yes, as a child (< 18 years)
 - Yes, as an adult (≥ 18 years)

48 **50b. Who subjected you to abuse as an adult (≥ 18 years)?**

- 49
50
51
52
53
54
55
56
57
58
59
60
- 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.

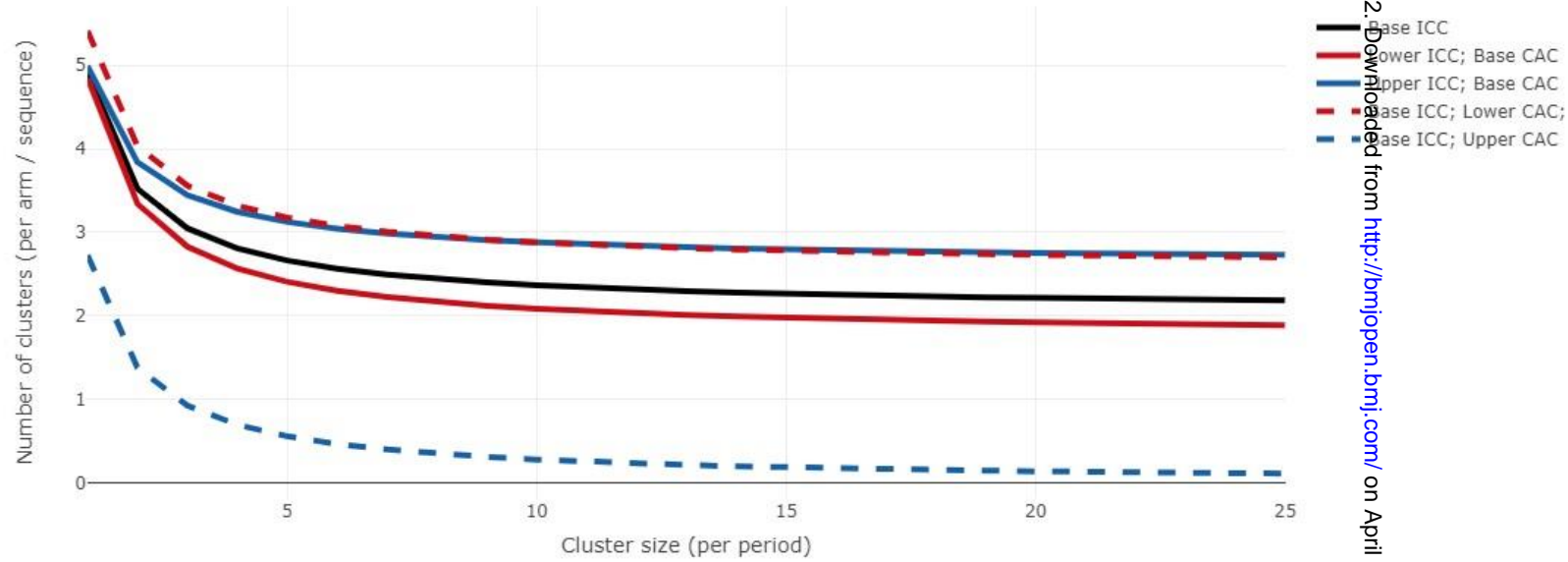
Reference: Simmons J, Motamedi A, Ludvigsson M, Swahnberg K. Testing an educational intervention to improve health care providers' preparedness to care for victims of elder abuse. A mixed method pilot study. Research Square [Preprint]. 2022. [Accessed 2022 April 2] <https://doi.org/10.21203/rs.3.rs-1510390/v1>

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

Downloaded from <http://bmjopen.bmj.com/> on April 20, 2024 by guest. Protected by copyright.

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 utbildningsdag kommer 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: dataskyddombud@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 forskningspersonsinformation.

Länk till webenkäten



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

Section/item	Item number	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

1			
2	Objectives	7	Specific objectives or hypotheses
3			5
4	Trial	8	Description of trial design including type of trial (eg, parallel
5	design		group, crossover, factorial, single group), allocation ratio, and
6			framework (eg, superiority, equivalence, noninferiority,
7			exploratory)
8			
9			
10	Methods: Participants, interventions, and outcomes		
11			
12	Study	9	Description of study settings (eg, community clinic, academic
13	setting		hospital) and list of countries where data will be collected.
14			Reference to where list of study sites can be obtained
15			
16	Eligibility	10	Inclusion and exclusion criteria for participants. If applicable,
17	criteria		eligibility criteria for study centres and individuals who will perform
18			the interventions (eg, surgeons, psychotherapists)
19			
20	Interventio	11a	Interventions for each group with sufficient detail to allow
21	ns		replication, including how and when they will be administered
22			
23			
24		11b	Criteria for discontinuing or modifying allocated interventions for a
25			given trial participant (eg, drug dose change in response to
26			harms, participant request, or improving/worsening disease)
27			
28			
29		11c	Strategies to improve adherence to intervention protocols, and
30			any procedures for monitoring adherence (eg, drug tablet return,
31			laboratory tests)
32			
33		11d	Relevant concomitant care and interventions that are permitted or
34			prohibited during the trial
35			
36	Outcomes	12	Primary, secondary, and other outcomes, including the specific
37			measurement variable (eg, systolic blood pressure), analysis
38			metric (eg, change from baseline, final value, time to event),
39			method of aggregation (eg, median, proportion), and time point
40			for each outcome. Explanation of the clinical relevance of chosen
41			efficacy and harm outcomes is strongly recommended
42			
43			
44	Participant	13	Time schedule of enrolment, interventions (including any run-ins
45	timeline		and washouts), assessments, and visits for participants. A
46			schematic diagram is highly recommended (see Figure)
47			
48			
49			
50	Sample	14	Estimated number of participants needed to achieve study
51	size		objectives and how it was determined, including clinical and
52			statistical assumptions supporting any sample size calculations
53			
54	Recruitme	15	Strategies for achieving adequate participant enrolment to reach
55	nt		target sample size
56			
57			
58	Methods: Assignment of interventions (for controlled trials)		
59			
60	Allocation:		

1				
2	Sequen	16a	Method of generating the allocation sequence (eg, computer-	N/A
3	ce		generated random numbers), and list of any factors for	
4	generati		stratification. To reduce predictability of a random sequence,	
5	on		details of any planned restriction (eg, blocking) should be	
6			provided in a separate document that is unavailable to those who	
7			enrol participants or assign interventions	
8				
9				
10	Allocatio	16b	Mechanism of implementing the allocation sequence (eg, central	N/A
11	n		telephone; sequentially numbered, opaque, sealed envelopes),	
12	conceal		describing any steps to conceal the sequence until interventions	
13	ment		are assigned	
14	mechani			
15	sm			
16				
17				
18	Implem	16c	Who will generate the allocation sequence, who will enrol	N/A
19	entation		participants, and who will assign participants to interventions	
20				
21	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial	N/A
22	(masking)		participants, care providers, outcome assessors, data analysts),	
23			and how	
24				
25				
26		17b	If blinded, circumstances under which unblinding is permissible,	N/A
27			and procedure for revealing a participant's allocated intervention	
28			during the trial	
29				

Methods: Data collection, management, and analysis

30				
31				
32	Data	18a	Plans for assessment and collection of outcome, baseline, and	9-10,
33	collection		other trial data, including any related processes to promote data	Table
34	methods		quality (eg, duplicate measurements, training of assessors) and a	1,
35			description of study instruments (eg, questionnaires, laboratory	Figure
36			tests) along with their reliability and validity, if known. Reference	1,
37			to where data collection forms can be found, if not in the protocol	Additio
38				nal file
39				1
40				
41				
42				
43		18b	Plans to promote participant retention and complete follow-up,	13
44			including list of any outcome data to be collected for participants	
45			who discontinue or deviate from intervention protocols	
46				
47	Data	19	Plans for data entry, coding, security, and storage, including any	10
48	manageme		related processes to promote data quality (eg, double data entry;	
49	nt		range checks for data values). Reference to where details of data	
50			management procedures can be found, if not in the protocol	
51				
52				
53	Statistical	20a	Statistical methods for analysing primary and secondary	10-11
54	methods		outcomes. Reference to where other details of the statistical	
55			analysis plan can be found, if not in the protocol	
56				
57		20b	Methods for any additional analyses (eg, subgroup and adjusted	10-11
58			analyses)	
59				
60				

- 1
2
3
4
5
6
7
- 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

8
9
10
11
12
13
14
15

Methods: Monitoring

- 16
17
18
19
20
21
22
23
24
25
26
27
28
29
- 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

30
31

Ethics and dissemination

- 32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
- 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

1				
2	Access to	29	Statement of who will have access to the final trial dataset, and	12
3	data		disclosure of contractual agreements that limit such access for	
4			investigators	
5				
6	Ancillary	30	Provisions, if any, for ancillary and post-trial care, and for	N/A
7	and post-		compensation to those who suffer harm from trial participation	
8	trial care			
9				
10	Disseminat	31a	Plans for investigators and sponsor to communicate trial results	12
11	ion policy		to participants, healthcare professionals, the public, and other	
12			relevant groups (eg, via publication, reporting in results	
13			databases, or other data sharing arrangements), including any	
14			publication restrictions	
15				
16				
17				
18		31b	Authorship eligibility guidelines and any intended use of	N/A
19			professional writers	
20				
21		31c	Plans, if any, for granting public access to the full protocol,	14
22			participant-level dataset, and statistical code	
23				
24				
25	Appendic			
26	es			
27	Informed	32	Model consent form and other related documentation given to	Additional file
28	consent		participants and authorised surrogates	3
29	materials			
30				
31				
32	Biological	33	Plans for collection, laboratory evaluation, and storage of	N/A
33	specimens		biological specimens for genetic or molecular analysis in the	
34			current trial and for future use in ancillary studies, if applicable	
35				

*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.