Statistical Analysis Plan

Responding to Elder Abuse in GERiAtric Care: Educational Intervention for Health Care Providers

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Responding to Elder Abuse in GERiAtric Care: Educational Intervention (REAGERA edu)

Background and rationale for study

The prevalence of elder abuse has been reported between 10-15% in international studies (Acierno et al., 2010; Pillemer, Burnes, Riffin, & Lachs, 2016; Yon, Mikton, Gassoumis, & Wilber, 2019; Yon, Mikton, Gassoumis, & Wilber, 2017). Elder abuse may include both physical, emotional, sexual and financial abuse as well as neglect and it occurs at the hand of both professionals and family members, including adult children and intimate partners. Elder abuse has been associated with psychological ill-health, disability, increased hospitalization, emergency department use and admission to nursing facilities (X. Dong, Chen, Chang, & Simon, 2013; X. Q. Dong, 2015; Fisher, Zink, & Regan, 2011; Schofield, Powers, & Loxton, 2013). Elder abuse is however often unknown to health care providers. Older adults are hesitant to disclose abuse and health care providers are often reluctant to ask questions. In this study we will use an interactive educational model consisting of theoretical lectures, as well as group discussions and forum theatre, a form of participatory theatre (Boal, 2000; Byréus, 2010). Both group discussions and forum theatre will be using case scenarios as a cornerstone.

In forum theatre the spectators are not only observers but rather spect-actors urged to participate in the scene. The forum theatre will start with the participants own experiences of meeting with patients as well as pre-constructed cases. The actors will act out each scene, showing for example a health care professional asking an older adult about abusive experiences in a suboptimal way. Participants are invited to at any time pause the scene and suggest alternative ways of acting. They are also encouraged to take the place of one of the actors, testing the consequences of another way of acting. In this way, participants are together exploring how their action may improve the health care encounter for abused older adults.

Figure 1 is an illustration of how learning activities during the education day is related to learning objectives and study outcome measures. The figure is replicated from a published study protocol (Ludvigsson, Motamedi, Westerlind, Swahnberg, & Simmons, 2022), which also describes in more details the theoretical assumption for the study as well as the content of the education. The description of study design and the planned statistical analyses that now will follow are at large part taken from that same publication (Ludvigsson et al., 2022).

Aim:

1) Investigate whether the education increases participants' propensity to ask questions about abuse.
2) Investigate whether the education affects participants' perceived barriers to asking questions, i.e., a) awareness and sense of responsibility to care for victims of abuse b) perceived ability to ask questions about abuse c) perceived preparedness to manage cases of elder abuse and d) perceived preparedness at the clinic to care for older adults subjected to abuse.

Study design:

The design is a non-randomised stepped wedge trial, a type of controlled cluster cohort study in which the participants gradually move from control group to intervention group (Brown & Lilford, 2006; Copas et al., 2015). In this study, a cluster entail a whole clinic or a unit at a clinic and at the end of the study all clusters will have completed the intervention, i.e., participated in the education. Data will be collected for all participants both pre- and post-intervention. Figure 2 illustrates the study design, including time plan. The intervention was originally planned to be rolled out during four periods between September 2021 and June 2023 (figure 2) and an incomplete design was chosen, i.e., six periods are used, but every cluster is only included at four measurement points: at baseline, in conjunction with the education, at six months follow up and at twelve months follow up. Similar incomplete designs have been described previously (Copas et al., 2015; Karla Hemming, Lilford, & Girling, 2015). For practical reasons the primary care centres included in the first study period had to be included later than the hospital clinics, i.e., in December 2021. To avoid a data collection period during the summer vacation, their first follow up was conducted nine months post intervention. Thereafter they will fall into the same pattern of data collection at six months interval as the other clinics. The six months interval was chosen because it provides an intermediate (six months) and long-term (twelve months) follow up that allows for a reasonable evaluation of the effect of the education. The times of data collection is illustrated in figure 2.

One geriatric clinic (cluster 8) and one primary health care centres (cluster 9) who were included at baseline decided in 2023 not to participate in the study for logistic reasons, e.g., having to prioritize other training for the staff. Therefor another primary health care centre was included (new cluster 8) and one training day was also open to participants from various primary health care centres (new cluster 9). For these clusters there is therefore no baseline data available, only pre-intervention data. In addition, the data collection phase had to be prolonged until September 2023.

Measurements:

Self-reported measurements will be collected with the questionnaire REAGERA-P, which has previously been validated in a Swedish health care professional sample (J. Simmons, Wenemark, & Ludvigsson, 2021).

Main outcome: Potential effect of the training on participants asking older patients questions about abuse. This will be measured as self-reported number of times the professional has asked patients questions about abuse (range 0-10 and above). The answers will be analysed both as a dichotomous variable (never/ one or more times) and as a continuous variable.

Secondary outcomes: Secondary outcome measures are items in REAGERA-P about the four main learning objectives of the education (figure 1). Changes in all variables between the measurement points will be considered.

1. **Awareness of elder abuse, sense of responsibility for identifying victims:**
    - Lack of awareness of elder abuse as a barrier towards identifying victims.
    - Perceived responsibility of the health care services as well as different health care professions to identify victims of elder abuse
    - Case vignette, measuring awareness and propensity for asking patients questions about abuse.
2. **Perceived ability to ask questions about abuse:**
    - Self-efficacy for asking questions about elder abuse.
    - Cause for concern that asking questions will a) lead to a negative reaction from the patient b) negatively impact the patient-provider relationship
3. **Preparedness to manage cases of elder abuse**
    - Self-efficacy for managing the response
    - Cause for concern that I will not be able to offer the patient a good follow up
    - Collegial support
    - Knowledge about proper documentation routines
    - Knowledge about judicial concerns
4. **Preparedness at the clinic to care for older adults subjected to abuse**
    - Deficient routines
    - Preparedness in the clinic and in society

Other outcome measures:

Anonymous data will be drawn from the medical records. It will consist of the number of time elder abuse have been recorded in the designated place in the digital medical record for each participating clinic. The validity of this data has not been established and it will therefore be considered an experimental outcome but could potentially be an objective assessment of whether the intervention leads to increased identification of patients subjected to elder abuse.

Some items in REAGERA-P does not directly measure any of the learning objectives of the education but could potentially be affected by the intervention and will hence also be considered. They are as follows:

- Proportion of respondents reporting that victims of elder abuse were given an adequate follow up.
- Proportion of respondents reporting suspecting elder abuse but refraining from asking questions.
- Proportion of respondents reporting changed working practice at follow up because of the education.

Covariates potentially affecting both the intervention effectiveness and the outcome will be considered. These include background characteristics of participants both on an individual and group level.

Eligibility

All health care professionals participating in the education at each clinic are eligible to participate in the study. Hence, for example a respondent belonging to cluster 4, that participate in data collection at step one but do not attend the education at step 3 (when he or she would be expected to attend) will be excluded. On the other side, a respondent from cluster 4 that do not respond to the baseline survey will still be included in the study as long as he or she attend the education at step 2. Personnel working solely administratively will be excluded.

Sample size

Cluster sample size was calculated using the Shiny CRT Calculator web application (Karla Hemming, Kasza, Hooper, Forbes, & Taljaard, 2020). Significance level was set to 0.05 and power to 0.8. We planned for a three-step intervention and used the discrete time decay. Initially we had planned a complete four period stepped wedge design and hence, that was used in the sample size calculation together with the discrete time decay. Divergent cluster sizes were expected and coefficient of variation for a cluster size was set at 0.5. Results from a pilot study (Johanna Simmons, Motamedi, Ludvigsson, & Swahnberg, 2022) was used to estimate cluster auto correlation at 0.6. Proportion

was set as outcome, and we used data from the pilot study to estimate the proportion under control at 0.26 and the proportion under intervention at 0.56. A cluster size of 10 then suffice to reach adequate power. Our smallest expected cluster has 31 participants and hence even with a response rate of less than 40% this is sufficient.

Statistical analysis

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

In a stepped wedge trial, results are compared across unexposed and exposed observation periods in the clusters, similar to the control and intervention arm in a parallel cluster trial (K Hemming, Haines, Chilton, Girling, & Lilford, 2015). The primary effect of this study will hence be calculated by comparing the main outcome (propensity to ask questions about abuse) in all clusters pre-intervention with all clusters post-intervention. Both mean difference in reported frequency of asking questions and changes in proportion of participants that report ever having asked questions about abuse will be reported. For the continuous outcome a linear mixed effect model will be used and for the binary outcome a generalised linear mixed effect model. The models will consider repeated measures and include cluster as random effect to determine if the anticipated effect of the model is dependent on the cluster, i.e., unit or clinic. During a stepped wedge trial more and more clusters will gradually transition from unexposed to exposed status, meaning that observation in the exposed status will on average be of a later date than the unexposed observation (K Hemming et al., 2015). This may introduce a bias in the study considering that there may be underlying temporal trends affecting the outcome, e.g., an increasing awareness of elder abuse in society over time. Therefore, both intervention status and time will be included as fixed effects in the models. Also, models will be adjusted for covariates, e.g., background characteristics, significantly associated with the outcome.

We propose that the education will work by participants overcoming personal and organizational barriers towards asking older patients questions about abuse. The items in REAGERA-P used to evaluate the effect on the different barriers and facilitators are described in figure 1 and they will be included in linear models (for continuous outcome) and generalised linear models (for binary

outcomes) to determine the effect of the intervention on these outcomes. If results support the theoretical model, efforts will be made to test if changes in perceived barriers mediate a potential effect of the intervention on the primary outcome, i.e., asking questions about abuse.

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

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

Figure 1. Theoretical model. An illustration of the alignment between learning activities (yellow), learning objective, that is, barriers and facilitators on a personal (green) and organisational (blue) level as well as evaluation (red). EA, elder abuse; REAGERA-P,Responding to Elder Abuse in GERiAtric care–Provider questionnaire.

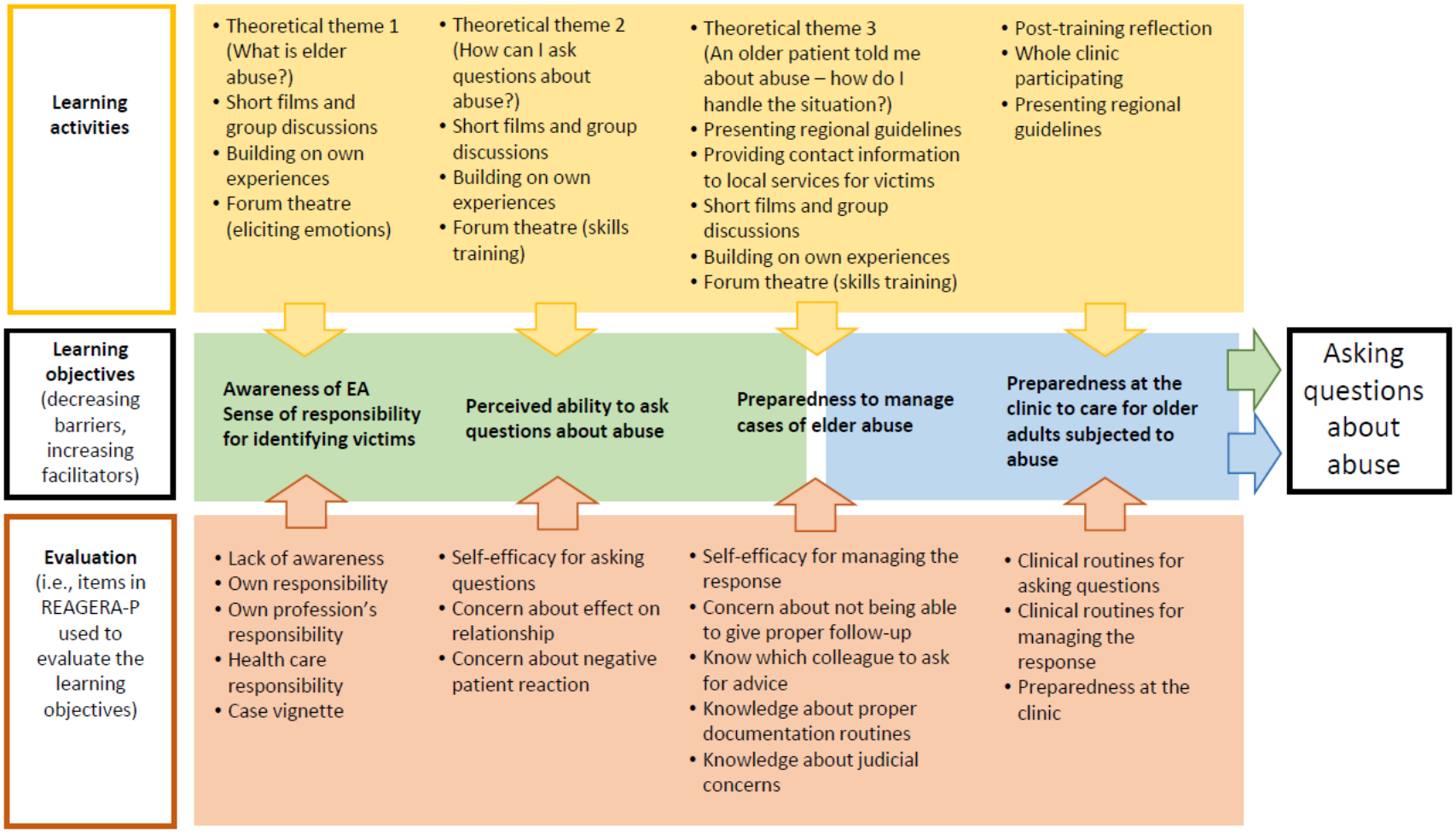
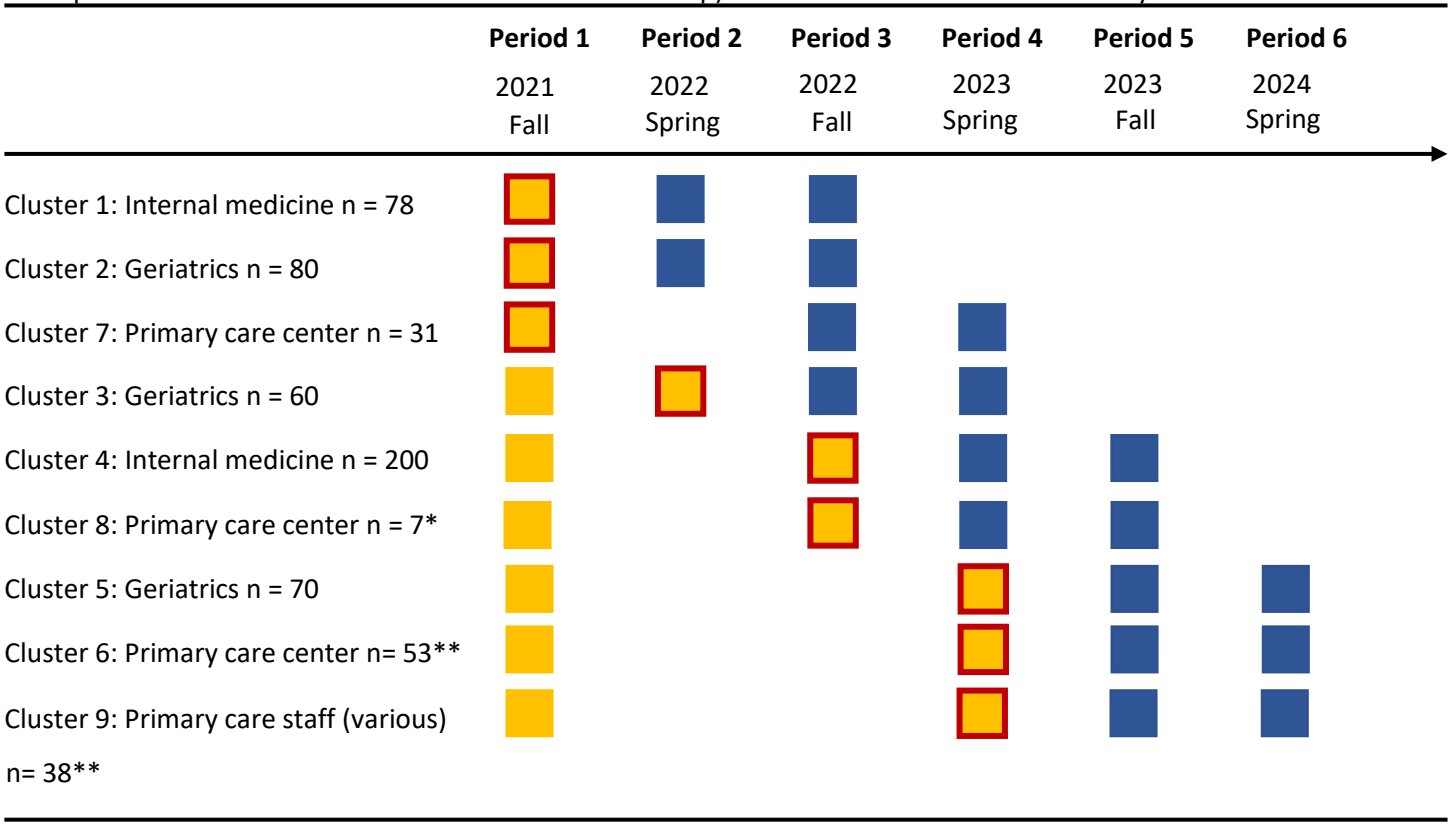


Figure 2 Design of the study and data collection points. An incomplete stepped wedge trial is planned. All clusters are measured pre-intervention (yellow squares=baseline and in conjunction with the educational day) and post-intervention (blue squares=at 6–8 months and 12–14 months of follow-up). Time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



*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 700. * Originally planned number of participants in cluster 8 was n=60. However, the primary care center decided against scheduling all employees, instead those wanting to participate had to register för it and only seven professionals did so*

*** Originally cluster 6 was planned to be a geriatric clinic and cluster 9 was planned to be a large primary care center. The clinics however decided to not participate and were therefore replaced by a smaller primary care center (new cluster 6) and a cluster open to staff from various primary care centers (cluster 9).*

Note:

A study protocol for this study has been published open access under a Creative Commons Attribution Non Commercial licens (CC BY-NC 4.0). Figure 1 and 2 as well as the text under the heddings "statistical analysis" and "study design" are derived from that publication.

Ludvigsson, M., Motamedi, A., Westerlind, B., Swahnberg, K., & Simmons, J. (2022). Responding to Elder Abuse in GERiAtric care (REAGERA) educational intervention for healthcare providers: a non-randomised stepped wedge trial. Bmj Open, 12(5), e060314. doi:10.1136/bmjopen-2021-060314 https://bmjopen.bmj.com/content/12/5/e060314

References

Acierno, R., Hernandez, M. A., Amstadter, A. B., Resnick, H. S., Steve, K., Muzzy, W., & Kilpatrick, D. G. (2010). Prevalence and correlates of emotional, physical, sexual, and financial abuse and potential neglect in the United States: the National Elder Mistreatment Study. *Am J Public Health, 100*(2), 292-297. doi:10.2105/AJPH.2009.163089

Boal, A. (2000). *Theatre of the oppressed*. London: Pluto Press.

Brown, C. A., & Lilford, R. J. (2006). The stepped wedge trial design: a systematic review. *BMC Medical Research Methodology, 6*(1), 54. doi:10.1186/1471-2288-6-54

Byréus, K. (2010). *Du har huvudrollen i ditt liv: om forumspel som pedagogisk metod för frigörelse och förändring*. Stockholm: Liber.

Copas, A. J., Lewis, J. J., Thompson, J. A., Davey, C., Baio, G., & Hargreaves, J. R. (2015). Designing a stepped wedge trial: three main designs, carry-over effects and randomisation approaches. *Trials, 16*(1), 352. doi:10.1186/s13063-015-0842-7

Dong, X., Chen, R., Chang, E. S., & Simon, M. (2013). Elder abuse and psychological well-being: a systematic review and implications for research and policy--a mini review. *Gerontology, 59*(2), 132-142. doi:10.1159/000341652

Dong, X. Q. (2015). Elder Abuse: Systematic Review and Implications for Practice. *J Am Geriatr Soc, 63*(6), 1214-1238. doi:10.1111/jgs.13454

Fisher, B. S., Zink, T., & Regan, S. L. (2011). Abuses against older women: prevalence and health effects. *J Interpers Violence, 26*(2), 254-268. doi:10.1177/0886260510362877

Hemming, K., Haines, T. P., Chilton, P. J., Girling, A. J., & Lilford, R. J. (2015). The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ : British Medical Journal, 350*, h391. doi:10.1136/bmj.h391

Hemming, K., Kasza, J., Hooper, R., Forbes, A., & Taljaard, M. (2020). A tutorial on sample size calculation for multiple-period cluster randomized parallel, cross-over and stepped-wedge trials using the Shiny CRT Calculator. *International Journal of Epidemiology, 49*(3), 979-995. doi:10.1093/ije/dyz237

Hemming, K., Lilford, R., & Girling, A. J. (2015). Stepped-wedge cluster randomised controlled trials: a generic framework including parallel and multiple-level designs. *Statistics in Medicine, 34*(2), 181-196. doi:https://doi.org/10.1002/sim.6325

Ludvigsson, M., Motamedi, A., Westerlind, B., Swahnberg, K., & Simmons, J. (2022). Responding to Elder Abuse in GERiAtric care (REAGERA) educational intervention for healthcare providers: a non-randomised stepped wedge trial. *Bmj Open, 12*(5), e060314. doi:10.1136/bmjopen-2021-060314

Pillemer, K., Burnes, D., Riffin, C., & Lachs, M. S. (2016). Elder Abuse: Global Situation, Risk Factors, and Prevention Strategies. *Gerontologist, 56*(Suppl_2), S194-S205. doi:10.1093/geront/gnw004

Schofield, M. J., Powers, J. R., & Loxton, D. (2013). Mortality and disability outcomes of self-reported elder abuse: a 12-year prospective investigation. *J Am Geriatr Soc, 61*(5), 679-685. doi:10.1111/jgs.12212

Simmons, J., Motamedi, A., Ludvigsson, M., & Swahnberg, K. (2022). Testing an educational intervention to improve health care providers' preparedness to care for victims of elder abuse: a mixed method pilot study. *BMC Medical Education, 22*(1), 597. doi:10.1186/s12909-022-03653-8. (Accession No. 35922855)

Simmons, J., Wenemark, M., & Ludvigsson, M. (2021). 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*(1), 473. doi:10.1186/s12913-021-06469-2

Yon, Y., Mikton, C., Gassoumis, Z. D., & Wilber, K. H. (2019). The prevalence of self-reported elder abuse among older women in community settings: a systematic review and meta-analysis. *Trauma, Violence, & Abuse, 20*(2), 245-259.

Yon, Y., Mikton, C. R., Gassoumis, Z. D., & Wilber, K. H. (2017). Elder abuse prevalence in community settings: a systematic review and meta-analysis. *The Lancet Global Health, 5*(2), e147-e156. doi:https://doi.org/10.1016/S2214-109X(17)30006-2