Preparing for the worst – promoting safety behaviours in antenatal care among Norwegian, Pakistani and Somali pregnant women. A randomised controlled trial

Analyses strategy

29th December 2017

The study will be conducted as an RCT where two groups will be compared, the group who received the intervention video and the group who received the control video.

All participants will be randomized to one of the groups. However to account for possible differences regarding the characteristics of the women participating in relation to socio-economic factors such as age, education, ethnic background, and economic status, data on these variables will be collected and used in multivariate analyses. We expect the randomization to ensure a similar distribution of medical and obstetric factors such as parity, gestational age at filling out the questionnaire, complication during pregnancy and BMI. However, if the groups are not balanced, these variables will be adjusted for in the multiple models.

We record at which healthcare center the women are recruited and at which hospital they give birth. Recruitment starts simultaneously at all health centers and finishes at the same time until the number of required women is reached. All women will be assessed for eligibility at these units.

We will perform stratified analyses for native Norwegian speakers and non-native Norwegian speakers as we anticipate possible differences between these groups.

Use of safety behaviors (main outcome 1)

The list of 15 safety behaviors was developed by Mc Farlane et al (2002 & 2004).

Women are asked to consider 15 safety behaviors. The answering options are yes, no, not applicable. The adjusted sum score is computed and adjusted for number of not applicable answers as follows:

: x= 15 * (a/b) where a/b is the proportion of recognized safety behaviors out of the number of applicable behaviors. Thus the adjusted total falls between 0 and 15. The equation used to calculate the adjusted total is: $a/b = x/15$, where a is the number of behaviors performed, *b* is the number of behaviors applicable, and x is the adjusted total. When *a* and *b* are known the adjusted total number can be calculated by cross-multiplying the two fractions.

For example: if a women performed 10 out of 11 applicable behaviors. Then a=10, divided by b=11.

$\frac{10}{11} = \frac{x}{15}$ $15.\frac{10}{11} = \frac{X}{15}.15$ $15.\frac{10}{15}$ = 13.63. the adjusted total is 13.6

Eller: x= 15 * (a/b) where a/b is the proportion of recognized safety behaviors out of the number of applicable behaviors.

The higher the score the higher number of safety promoting behaviors performed. Our hypothesis is that an increase of number of safety promoting behaviors is positive. We also hypothesize that the increase will be higher among women who watch the intervention video compared to the control video.

Little is known about our study population in general and there is little information in the literature regarding anticipated mean values and SD for the measurements before and after the intervention. Moreover, little is known what would be considered a clinically meaningful change. Therefore we based our power calculation on 'worse scenario' with low number of safety behavior at baseline and very small change after the intervention. We do not anticipate any change before and after for the control group. Thus using McNemar's test for correlated proportions as the same women are interviewed before and after the intervention we anticipate that the proportion before (a/b) would be 20% (3 behaviors out of 15) and this proportion would increase to 30% (5 safety behaviors). Further

assuming the responses to be moderately correlated (0.6) we would need 75 women in both groups to keep power of 87% and alpha of 5%. If the correlation is weaker (0.5) we would have power of 80% given the same sample size.

We anticipate larger proportions of safety behavior and especially a large positive change after the intervention so with 75 women in both groups we consider our study to be sufficiently powered.

The groups will be compared at baseline using descriptive statistics (continuous variables will be compared using t-tests of Mann-Whitney Wilkoxon tests and categorical variables will be analysed using a X^2 test).

Multiple mixed models with the unit as a random effect and selected covariates will be fitted to assess the possible effect of the intervention. Further, we will assess a possible effect of health center which the participants attended on the safety behavior – both

If there are significant differences between the health centers we will adjust for this in the multiple model as a fixed covariate, if there is an interaction between a group (intervention vs control) and a health center variable, we will present stratified analyses. There are 20 health centers which will be categorized as follows: Either based on the size, grouping small (less than 100 women a year), medium (from 100 to 300 women a year) and large centers (more than 300 women a year). Alternatively, we will compare the health centers in Oslo city with those outside Oslo city.

We will further perform a logistic regression analysis (Mc Farlane 2002) to investigate group differences in safety behaviors applicable to at least 90% of the women

Mc Farlane, J.; Malecha, A.; Gist, J.; Watson, K.; Batten, E.; Hall, I.; Smith, S. (2004) Increasing the safety-promoting behaviors of abused women *Am J Nurs* Vol. 104(3):40-50

McFarlane, Judith; Malecha, Ann; Gist, Julia; Watson, Kathy; Batten, Elizabeth; Hall, Iva; Smith, Sheila An intervention to Increase Safety behaviors of Abused Women: Results of a Randomized Clinical Trial (2002) *Nurs Res* Nov-Dec 51(6):347-54

Mcfarlane, Judith ; Parker, Barbara ; Soeken, Karen ; Silva, Connie ; Reel, Sally (1998) Safety Behaviors of Abused Women After an Intervention During Pregnancy *Journal of Obstetric, Gynecologic, & Neonatal Nursing,* January 1998, Vol.27(1), pp.64-69

WHOQOL-BREF (main outcome 2)

Quality of life will be measured with the WHOQOL-BREF (1).The WHOQOL-BREF is an abbreviated 26-item version of the WHOQOL-100. The WHOQOL-BREF is a shorter version of the original instrument and more convenient to use in large research studies or clinical trials. It consists of two global items on overall quality of life and general health, and four domains: Physical health domain (7 items), Psychological domain (6 items), Social relationships domain (3 items), and Environmental domain (8 items). This generates a profile of domain scores. The two additional items will be examined separately: the overall perception of quality of life and overall perception of health. Each item is scored on a Likert scale ranging from 1 to 5. The items ask the respondent "how much," "how often," "how completely," "how good" or "how satisfied" she felt about different aspects of her life in the past 2 weeks. The mean score of the items within each domain is transformed linearly to a domain score scaled in a positive direction from 0–100, such that higher scores indicate higher quality of life (1). One domain will be excluded from the analysis if >20% of data is missing from an individual assessment, as recommended in the WHOQOL-Bref manual (1).

The instrument has previously been translated into Norwegian, Urdu and Somali according to existing internationally accepted guidelines, and has shown satisfactory results regarding validity and reliability (2).

We will use paired-samples t-test to evaluate the crude impact of the intervention on the quality of life score. Further linear regression models will be fitted to assess the possible differences between the groups adjusted for selected confounders. We will compare the mean (SD) score within each domain and each of the two overall items.

1.Organization WH. WHOQOL User Manual. Geneva: WHO; 1998.
2.Hanestad BR, Rustoen T, Knudsen O, Jr., Lerdal A, Wahl AK. Psychometric properties of the WHOQOL-BREF questionnaire for the Norwegian general population. Journal of nursing measurement. 2004;12(2):147-59.

Childbirth experience (secondary outcome)

We will use the following question to assess childbirth experience:

How did you experience your birth?

- An entirely positive experience
- A positive experience with negative elements
- A negative experience with positive elements
- An entirely negative experience

This question has been used in the Bidens study and has been dichotomised for analyses in a positive or a negative experience. We will the intervention and control group for the proportion of negative birth experiences use X^2 tests and logisitic regression analyses. We will adjust analyses for mode of delivery.

M. Lukasse, A.M. Schroll, E.L. Ryding, J. Campbell, H. Karro, H. Kristjansdottir, B. Schei(2014) Prevalence of emotional, physical and sexual abuse among pregnant women in six European countries *ACTA Obstetricia et Gynecologica Scandinavica*, (93) pp. 669-677,

Henriksen L, Grimsrud E, Schei B, Lukasse M (2017)Factors related to a negative birth experience – A mixed methods study *Midwifery* Vol 51, pp 33-39

Edinburgh Depression Scale-5 short version (secondary outcome)

Eberhardt-Gran et al (developed and validated a short version (in Norwegian) of the original Edinburgh Depression Scale.

This instrument consists of 5 questions. Each question has four response options, ranging from 0 to 3. Thus, the total score has a minimum of 0 and a maximum of 15. The total score is calculated and then a cut-off score of ≥ 7 of more is used. A score of 7 or more is considered an indication of the presence of symptoms of depression.

We will compare the proportion of women with a cut-off score of 7 or more between the women who viewed the intervention video and the control video.

Odd Ratio's with 95% CI Crude differences before and after the intervention for both groups will be assessed using the McNemar's test.

To adjust for baseline levels of EDS we will fit a logistic regression model with the baseline values as a covariate. Further we will adjust for other relevant possible confounders in addition to assessing the difference between the intervention and control groups. The results will be expressed as

Eberhard-Gran, M.; Eskild, A.; Samuelsen, S.O.; Tambs, K. (2007) A short matrix-version of the Edinburgh Depression Scale *Acta Psychiatr Scand* Vol. 116(3):195-200

Obstetric and neonatal outcomes (secondary outcome)

We will compare differences in the proportion of women in the intervention group with the proportion of women in the control group for the following outcomes: use of epidural analgesia, use of water, use of pudendal, spontaneous vs. operative birth, low vs. normal birthweight, breastfeeding vs. not breastfeeding. We will use Pearson's X^2 test of Fishers exact (if less than 5 in one of the cells) and logistic regression analyses.

Confounding factors for spontaneous vs. operative birth are Body Mass Index, previous CS.

Composite Abuse Scale (CAS) (secondary outcome)

CAS $_R$-SF is a 15-item instrument that captures physical, sexual and psychological abuse and overall Intimate Partner violence (IPV) (3). The CAS $_R$-SF is based on the 30-item Composite Abuse Scale, which is widely used to assess women's self-reported experience of violence in an intimate relationship (4). The CAS $_R$-SF was developed to improve the CAS regarding response burden, brevity and clarity (3).

Women will be asked 15 questions about different actions and have the possibility to answer: Have this ever happened to you? Yes/No. If yes, how often did it happened in the last 12 month: Not in the past 12 months, once, a few times, monthly, weekly, daily/almost daily (0 to 5 scale). Total scores for the CAS$_R$-Sf, ranging from 0 to 75, will be calculated by computing mean of past 12-month frequency of abuse and multiplying by 15. For the questionnaire to be valid, less than 4 (out of 15) items can be missing. Subscale scores will be calculated for the physical, sexual and psychological abuse in a similar manner. We will use paired sample t test to compare the mean score before and after the intervention in both groups (intervention vs control). Further linear regression models adjusted for baseline measurements and selected possible confounders will be fitted.

3. Ford-Gilboe M, Wathen CN, Varcoe C, MacMillan HL, Scott-Storey K, Mantler T, et al. Development of a brief measure of intimate partner violence experiences: the Composite Abuse Scale (Revised)-Short Form (CASR-SF). BMJ Open. 2016;6(12):e012824.
4. Hegarty K, Sheehan M, Schonfeld C. A Multidimensional Definition of Partner Abuse: Development and Preliminary Validation of the Composite Abuse Scale. Journal of Family Violence. 1999;14(4):399-415.