

Pre-Analysis Plan

Effect of extended trading hours on alcohol sales in Norway: a cluster randomised controlled trial

Developed in accordance with the SPIRIT checklist for clinical trial protocols (Chan, Tetzlaff et al. 2013). Items in this pre-analysis plan are structured identically to the recommend items in the checklist. Due to the non-clinical setting of this trial, adaptations are made and some items from the checklist are not applicable.

Administrative Information

1. Title

Effect of extended trading hours on alcohol sales in Norway: a cluster randomised controlled trial

2. Trial Registration

2a. AEA RCT Registry, trial identifier no. AEARCTR-0006290

First registration: August 18, 2020

2b. WHO Data Set enclosed

3. Protocol version

13.08.2020 - Protocol version 1

4. Funding

Internal funding by the Norwegian Institute of Public Health (NIPH)

5. Roles and responsibilities

5a. The Norwegian Ministry of Health and Care requested the NIPH to evaluate possible effects of extended trading hours in the state-owned monopoly on strong beer, wine, and spirits, Vinmonopolet.

The study will be conducted by a research team at the NIPH. This team includes Researcher Daniel Bergsvik¹ (DB), Researcher Maja W. Grøtting² (MG), and Research Professor Ingeborg Rossow³ (IR), all affiliated with the NIPH.

IR is principal investigator (PI) and initiated and managed the correspondence with Vinmonopolet as well as conducted the formal registration. Co-author of protocol.

DB is co-PI and in charge of data simulations, power analysis, and randomisation. Co-author of protocol.

MG is co-PI, in charge of writing the protocol. Assisted in the simulations and randomisation.

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All listed researchers initiated and completed the study design and participated in preliminary meetings with Vinmonopolet.

5b. NIPH is the trial sponsor.

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5c. The research team at NIPH is solely responsible for study design; collection, management, analysis, and interpretation of the data; writing of the report; and the decision to submit the report for publication.

5d. Vinmonopolet (the state-owned monopoly) is responsible for coordinating and managing the implementation of the trial and most of the data collection. The research team at NIPH is responsible for the experimental design, randomisation, data analysis, and publications. The Norwegian Ministry of Health and Care requested the NIPH to conduct an evaluation of possible effects of extending the trading hours. The Ministry has no further role in the project.

Introduction

6. Background and rationale

6a. Alcohol consumption is among the leading risk factors for health and social problems in the population, both globally as well as in high income countries (Babor, Caetano et al. 2010, Shield, Manthey et al. 2020). Regulation of alcohol availability through measures of restricted access is one of the most effective policies to curb alcohol consumption and related harms (Babor, Caetano et al. 2010).

In Norway, alcohol policy contains a number of policy measures regulating access to alcohol. One such measure is the state-owned monopoly (called Vinmonopolet) for all retail off-premise sales of alcoholic beverages over 4.7 percent alcohol (i.e. strong beer, wines and spirits). The number of alcohol monopoly outlets is restricted; in Norway, with a population of 5 million inhabitants, there are currently 335 such outlets. Retail off-premise sales of alcohol with lower alcohol content (mainly medium strength beer) is allowed in licensed grocery stores, which are far more numerous (currently around 4 000 stores) than the monopoly outlets. Another important measure to regulate access to alcohol in Norway, is restriction of trading hours. As per August 2020, the maximum national limits for off-premise alcohol sales are as follows: In grocery stores, the trading hours are between 8:00 am and 8:00 pm Monday through Friday and between 8:00 am and 6:00 pm on Saturdays. In alcohol monopoly outlets, the maximum trading hours are more limited; as per August 2020 they are between 8:30 am and 6:00 pm Monday through Friday and between 8:30 am and 3:00 pm on Saturdays. No off-premise alcohol sales are allowed on Sundays (or on other public holidays, Constitution day, etc.).

In recent years, shopping patterns among Norwegian customers are altered, with stronger preferences for shopping on Saturday afternoons. In response to this change in shopping pattern, the owner of Vinmonopolet, the Ministry of Health and Care Services, proposed to the Parliament a change in the Alcohol Act, allowing for alcohol sales in monopoly outlets until 4:00 pm on Saturdays. The proposed change included also that monopoly outlets were allowed to open at the earliest at 10:00 am on Saturdays. The proposed change was likely grounded in a concern for maintaining legitimacy among Norwegian consumers, as public support for this state monopoly is vital for its future existence. The Ministry's proposal was adopted by the Parliament in June 2020, and the

change in trading hours on Saturdays could take effect from September 1st 2020. While the change in the Act is – formally – only an offset of trading hours on Saturdays, the reality is that most of the monopoly outlets currently open at 10:00 am on Saturdays. Thus, the adopted change in the Alcohol Act, implies in effect an extension of trading hours by one hour for most monopoly outlets.

Although one extra trading hour is a small increase compared to total access throughout the week, the extended access comes at a critical time. Between 2:00 pm and 3:00 pm is when most outlets experience the highest sales per hour throughout the week. The increase in access, therefore, comes at a time when demand is exceedingly high and potentially more elastic. Thus, it can be argued that the current closing time, at 3:00 pm, is a particularly binding constraint.

The trading hours are, as noted, wider for sales of low content alcohol (mainly medium strength beer) in licensed grocery stores compared to alcohol sales in monopoly outlets. With an extension of trading hours in monopoly outlets from 3:00 pm to 4:00 pm, it may be expected that alcohol sales in monopoly outlets increase slightly. It is further possible that there will be some trade leakage from alcohol sales in grocery stores to that in monopoly outlets. In other words; a possible increase in alcohol sales in the state monopoly due to an increase in trading hours, may in part be substituted by a small decrease in alcohol sales in grocery stores, reflecting trade leakage. From a public health point of view, changes in total alcohol consumption are of key interest. It is well demonstrated that an increase in total alcohol consumption in a society is accompanied by an increase in health and social problems at the population level, and vice versa (Babor, Caetano et al. 2010, Holmes, Meier et al. 2012, Kehoe, Gmel et al. 2012). On-premise alcohol sales constitute a minor fraction (10 – 15 %) of total alcohol consumption in Norway, and hence total off-premise alcohol sales is a good proxy for total alcohol sales and total alcohol consumption.

The Ministry of Health and Care Services requested the Norwegian Institute of Public Health (NIPH) to evaluate possible effects of the change in trading hours. With this project, we aim to investigate possible effects on alcohol sales of the planned small extension of trading hours in alcohol monopoly outlets. Specifically, we aim to evaluate whether this increase in trading hours results in 1) an increase in alcohol sales in the monopoly outlets, and 2) an increase in total alcohol sales, including possible substitution effects from beer sales in grocery stores.

Regulating days and hours of trading of alcohol in licensed off-premise outlets is a widely used policy measure. The research literature is quite consistent in acknowledging regulation of access to alcohol as an effective policy measure to curb consumption and harms, including measures restricting the days and hours of sale (Babor, Caetano et al. 2010, Sherk, Stockwell et al. 2018, Nepal, Kypri et al. 2020). However, much of this literature pertains to on-premise trading hours, and there is less evidence of possible effects of changes in days and hours of off-premise trading (Wilkinson, Livingston et al. 2016, Sanchez-Ramirez and Voaklander 2018, Sherk, Stockwell et al. 2018, Nepal, Kypri et al. 2020). Sherk and colleagues (2018) conducted a meta-analysis of six studies examining the effect of allowing a one day change in off-premise alcohol sales (either Saturdays or Sundays) and estimated that an additional day of trading led to an increase in total alcohol sales by 3.4 %. Studies examining effects of changes in hours of off-premise trading on consumption or sales are even fewer. Sherk et al. (2018) identified only one such study, which showed that in Russian regions, restrictions on hours of off-premise sales – particularly late at night – led to reduced consumption levels (Kolosnitsyna, Sitdikov et al. 2014). Two studies, from Germany (Marcus and Siedler 2015) and from Switzerland (Wicki, Bertholet et al. 2020), found that restrictions in off-premise trading hours late at night led to reductions in alcohol related harms. Thus, results from this planned project will add to a meagre literature on possible effects of a change in trading hours in off-premise alcohol outlets.

Controlled experiment designs are rarely used in evaluations of possible effects of a change in alcohol availability. Studies applying such designs, typically come from the Nordic countries; some conducted in the 1970s-80s (Mäkelä, Rossow et al. 2002), and a few in more recent years. The latter studies pertain to evaluations of transfer from over-the-counter to self-service in Sweden (Skog 2000) and in Norway (Horverak 2008), and the effects of Saturday openings of outlets in Sweden (Norström and Skog 2003, Norström and Skog 2005). Notably, these experiments were all conducted in state alcohol monopolies. While the previous experiments were designed with designated intervention and control conditions, this planned project will apply a randomised controlled trial design.

Thus, the planned randomised controlled experiment offers a rare opportunity to study possible effects of a relatively small change in a widely used alcohol policy measure.

6b. Explanation for choice of comparators is not applicable

7. Objectives

The primary objectives with this study are to test empirically whether, and if so to what extent, the planned extension of trading hours results in 1) an increase in alcohol sales in the monopoly outlets, and 2) an increase in total alcohol sales, including possible substitution effects from beer sales in grocery stores.

The key secondary objectives are to explore how extended opening hours affects sales across days of the week or across sale hours on Saturday, and how weekly sales and sales in turnover (NOK) are affected by the extension of opening hours.

In addition, as part of robustness and sensitivity analyses, we will explore whether a possible effect of extended trading hours vary by certain characteristics of trade districts, including high sales volumes, proximity to the Swedish border and regional coronavirus measures.

8. Trial Design

The trial is designed as a cluster randomised controlled trial. Monopoly outlets are clustered into trade districts to reduce spill-over effects caused by trade leakage across monopoly outlets. Due to substantial variation in alcohol sales across trade districts, the 62 (of 66⁴ in total) trade districts eligible for randomisation were stratified into three blocks, based on monthly alcohol sales in 2018. Computer-generated randomisation of trade districts allocated monopoly outlets within each block into one of three experimental conditions: implementation of extended trading hours by September 1st 2020⁵, by December 1st 2020, or by March 1st 2021. Extended trading hours will take effect on the same date for all monopoly outlets within a trade district. After implementation, extended trading hours will remain the same throughout the study period.

⁴ Note that the total number of trade districts in Norway is presented differently in the trial registration; that is n=67. According to an internal report by the state monopoly, where they have identified and presented the trade districts, the total number of trade districts is presented as 67. However, in recent files from the state monopoly, the number of trade districts is 66.

⁵ The first Saturday is September 5th. Correspondingly, first Saturdays are December 5th and March 6th.

Methods: Participants, interventions, and outcomes

9. Study Settings

The geographic location of the experiment is Norway, the whole country (with the exception of Svalbard). Retail data on alcohol sales will be collected from all monopoly outlets and from the vast majority (95 percent) of grocery stores in Norway.

10. Eligibility Criteria

There are currently 335 monopoly outlets in Norway distributed over 66 trade districts (as identified by Vinmonopolet). In June 2020, Vinmonopolet agreed to implement the extension of trading hours within a randomised controlled trial design, although with some adjustments. Vinmonopolet requested that the monopoly outlets in 4 large cities (Oslo, Bergen, Trondheim and Tromsø) be exempt from the experiment, that is; the state monopoly wished to implement the extended trading hours in these four cities at the earliest time point (September 1st 2020). There are altogether 54 outlets in these four cities. Two of these cities (Oslo and Trondheim), each constitute a trade district, whereas Bergen and Tromsø both are part of a larger trade district. This requested exemption implied that two trade districts were not eligible and two other trade districts were eligible, but with some excluded outlets.

There is large variation in number of outlets per trade district, and there is huge variation in overall alcohol sales and sales on Saturday afternoons across outlets and across trade districts. In order to allow Vinmonopolet some flexibility with regard to whether and when to implement extended trading hours, the 50 outlets with the smallest alcohol sales on Saturday afternoon were exempt from the experiment. These 50 outlets were identified by sales data from 2018. Since then, an additional five monopoly outlets have opened. Three of these have very low alcohol sales and were therefore added to the outlets with the smallest alcohol sales, thus totalling 53 outlets. Notably, these outlets account for a negligible part of the overall sales and are therefore of minimal interest for the experimental design. In two trade districts, all outlets (two in each district) were among the 53 smallest outlets, and thus, these two trade districts were not eligible.

Thus, out of 335 outlets and 66 trade districts, 228 outlets and 62 trade districts were eligible for trial inclusion.

All 54 outlets in the four large cities will be under the same regime as those in the first experiment condition (i.e. extended opening hours as from September 1st 2020). The state monopoly has further allocated 52 of the 53 outlets with the smallest sales to implement extended trading hours by September 1st 2020, while the remaining one outlet with small sales will have extended trading hours from December 1st 2020. We will collect data from all monopoly outlets, including those that are not part of the randomised trial. The latter will be used in additional analyses.

11. Interventions

11a. All eligible trade districts are allocated to one of three experiment conditions. The first experiment condition implies extended trading hours (from 3:00 pm to 4:00 pm on Saturdays) taking effect from September 1st 2020. The second experiment condition is the same extension in trading hours but taking effect December 1st 2020. The final experiment condition is no extension of trading hours until March 1st 2021, when the same extension of trading hours will take effect.

In 21 trade districts, extended trading hours will be implemented from September 1st 2020; in 21 other trade districts, extended trading hours will be implemented from December 1st 2020; and in the remaining 20 trade districts, extended trading hours will be implemented from March 1st 2021. Extended trading hours will take effect on the same date for all monopoly outlets within a trade district. After implementation, extended trading hours will remain the same throughout the study period.

11b. An outlet will be discounted from the experiment in the event of an outlet closure. Currently, there are no planned closures.⁶ Vinmonopolet is – in principle – free to discontinue the experiment in any form they chose and at any time. Experiences from previous controlled experiments within Vinmonopolet, suggest that the risk of such discontinuation is small (Mäkelä, Rossow et al. 2002, Horverak 2008).

11c. Vinmonopolet manages all outlets and possesses perfect control over trading hours. A strategy for improving adherence is therefore not applicable.

11d. Concomitant care and permitted interventions are not applicable.

12. Outcomes

Key outcome variables are

- i) monthly alcohol sales in monopoly outlets
- ii) monthly alcohol sales in licensed grocery stores

Both measured in beverage specific volumes and in litres of pure alcohol.

Secondary outcomes are

- i) weekly alcohol sales in monopoly outlets and in licensed grocery stores
- ii) distribution of total alcohol sales over days of the week (Monday through Saturday) in monopoly outlets
- iii) distribution of alcohol sales over the trading hours on Saturdays in monopoly outlets,

These are measured in beverage specific volumes and in litres of pure alcohol

- iv) monthly alcohol sales (total and beverage specific) in monopoly outlets, as measured in turnover (NOK).

Data on alcohol sales are provided in litres and in NOK per beverage category, and will be calculated into litres of pure alcohol. The variables will also be adjusted for seasonal variation.

Data on alcohol sales are collected routinely by Vinmonopolet for the monopoly outlets (per outlet, per week, and per trading hour on Saturdays) and from AC Nielsen for sales in grocery stores (per grocery store, per week).

Finally, we will collect data on trade district characteristics, such as proximity to Swedish border, tourism, and demographic characteristics of the population in each trade district that are publicly available at Statistics Norway.⁷

⁶ The outlet at Holmlia in the city of Oslo (exempt from experiment) is currently closed and will re-open in the autumn of 2021.

⁷ These data are available at the municipality level.

13. Participant timeline

Before September 1st 2020: All outlets close at 3:00 pm on Saturdays.

September 1st 2020: Trading hours in outlets allocated to the first experiment condition are extended from 3:00 pm to 4:00 pm on Saturdays. Outlets allocated to the second and third experiment condition continue with trading hours until 3:00 pm on Saturdays.

December 1st 2020: Trading hours in outlets allocated to the second experiment condition are extended from 3:00 pm to 4:00 pm on Saturdays. Outlets in the first experiment condition continue extended trading hours to 4:00 pm. Outlets in the third experiment condition continue with trading hours until 3:00 pm.

March 1st 2021: Trading hours in outlets allocated to the third experiment condition are extended from 3:00 pm to 4:00 pm on Saturdays. All other outlets continue extended trading hours to 4:00 pm.

March – December 2021: Post intervention observation period. All outlets are open until 4:00 pm.

We will collect data from 6 years prior to experiment start (that is from September 1st 2014) until February 28th 2022, with a possible extension of almost two years (that is until December 31st 2023). These sales data are produced routinely by Vinmonopolet and available for the research team.

The outlets in the non-eligible group of the four large cities will follow the same regime as those allocated to the first experimental condition (extended opening hours from September 1st 2020 and throughout the study period). Correspondingly, 52 of the 53 smallest outlets will have extended trading hours from September 1st 2020, whereas the remaining one (out of the 53 smallest outlets) will have extended trading hours from December 1st 2020.

The timeline of the experiment is presented in a schematic diagram in the file “Timeline Diagram”.

14. Sample size

Altogether 228 monopoly outlets, distributed over 62 trade districts, are included in the experimental design. A total of 82 outlets, distributed over 21 trade districts, are allocated to the first experiment condition (extended trading hours take effect September 1st 2020); 71 outlets, distributed over 21 trade districts, are allocated to the second experiment condition (extended trading hours take effect December 1st 2020), and 75 outlets, distributed over 20 trade districts, are allocated to the third experiment condition (extended trading hours take effect March 1st 2021).

Power calculations were conducted as follows. Simulations were performed employing real sales data from January 2014 to August 2019. In these simulations, we assumed that extended opening hours were implemented by trade districts from September 1st 2018, December 1st 2018, and March 1st 2019, thus resembling the dates of the planned experiment, only two years before. For each outlet, the predicted increase in sales was set to be a uniformly distributed rate over the interval (0, 0.3) of mean hourly sales on Saturday afternoons in 2018; and this effect was further weighted by a relative measure of increasing sales on Saturday afternoons as compared to sales in the morning hours. The simulated increase in sales on Saturdays, given a one hour increase in trading hours, was then added to monthly sales data on which we ran regressions with standard errors clustered at the trade district level. In the regression models, we also accounted for seasonal variation. With 100 simulations of different block randomizations and random effect sizes, we were unable to produce parameter estimates for wine (mean $\beta=0.030$) and spirits (mean $\beta=0.025$) which were not statistically significant at $p < 0.05$. However, the effect on beer sales (mean $\beta=0.018$) was mostly statistically insignificant.

In additional analyses, we plan to include the 107 excluded outlets accordingly: i) include only the 54 outlets from the 4 excluded large cities, ii) include only the 53 smallest outlets, and iii) include all 107 excluded outlets.

15. Recruitment

Vinmonopolet is responsible for all monopoly outlets in Norway and has committed to the experimental design and randomisation of outlets.

Methods: Assignment of interventions (for controlled trials)

16. Allocation

16a Sequence generation. All eligible districts are divided into three blocks according to rank of monthly sales on Saturdays. Trade districts are then allocated to one of the three experimental conditions by computerized random number generation within each block. A random number generator in STATA was applied for the block-randomization.

16b Allocation concealment mechanism. The division of trade districts allocated into the different experimental conditions was sent to Vinmonopolet in June 2020, so as to allow time for preparing implementation according to the design.

16c Implementation. Vinmonopolet is responsible for communicating with the different outlets and managing the variations of opening hours across trade districts.

17. Blinding

17a. As the intervention is an extension of opening hours, blinding is not applicable.

17b. NA

Methods: Data collection, management, and analysis

18. Data collection methods

18a. Vinmonopolet collects routinely data on beverage specific alcohol sales, measured both in litres and in NOK per outlet and per day and hour for all their outlets. These data will be provided for the period September 2014 to March 2022. A private company, AC Nilsen collects data routinely on sales of low content alcoholic beverages (up to 4.7 percent), measured both in litres and NOK, per outlet and per week for the vast majority (95 percent) of grocery stores in Norway. We will obtain data for district specific characteristics from Vinmonopolet and publicly available demographic controls from Statistics Norway.

18b. Data will also be collected for outlets excluded from the experiment and possibly for a longer follow-up period (until December 2023).

19. Data management

The data are not sensitive and will be kept, quality checked, and analysed by the research team at NIPH. Vinmonopolet collects sales data on a regular basis. These will be sent by email in excel to the research team at NIPH. Quality checking of the data includes assessing outliers in sales and comparing sales at specific outlets with over-all sales trends.

20. Statistical methods

20a. Ordinary regression analyses will be applied to analyse the data. The main output is monthly sales in litres of pure alcohol (total and beverage specific), adjusted for seasonal variation (using sales in the same month in the preceding years). Depending on the data, it may also be necessary to account for spikes in sales on Saturdays before major public holidays. If so, results with and without accounting for these spikes will be reported. The unit of analysis is monopoly outlet, and standard errors will be clustered at the trade district level. Results will be reported using a 5% level of statistical significance. The following controls may be included in the analysis: population size, proximity to the Swedish border (proxy for trade leakage), tourism, and number of monopoly outlets in the trade district. Trade district fixed effects will be included. In addition, the effect of coronavirus measures will be considered if appropriate. Finally, there is anecdotal evidence from Vinmonopolet, suggesting that lagged response to changes in opening hours may occur in some regions. We will therefore assess effects in the short and the intermediate term with the possibility of interactions with region/trade district.

Finally, we will explore how extended opening hours affects weekly sales, sales across days of the week or across sale hours on Saturday, and sales in turnover (NOK).

20b. Robustness checks and sensitivity analyses will include the following:

- Inclusion of all trade districts and outlets that were not eligible for the RCT in the main analyses, and compare estimates
- Assessing the effects for the following sub-groups:
 - o The block with the highest sales volumes
 - o The trade districts closest to the Swedish border, where trade leakage is most common (thereby taking into account possible variations in travel restrictions due to coronavirus measures)

20c. The issue of missing data is seen as minimal as we expect that only outlet closures will lead to missing data. As of now (August 2020), no closures are expected.⁸

Methods: Monitoring

21. Data monitoring

21a. Vinmonopolet continuously monitors sales and opening hours in all outlets.

21b. There are no stopping guidelines. However, Vinmonopolet can terminate the experiment at any point in time.

22. Harms

We expect no adverse or unintended effects of the experiment.

23. Auditing

There are no plans of auditing of the trial conduct.

⁸ One outlet in Oslo (excluded trade district) will be closing during the study period.

Ethics and dissemination

24. Research ethics approval

Non-applicability of IRB approval is obtained from an internal review board at NIPH.

25. Protocol amendments

There are no plans for important protocol modifications.

26. Consent or assent

26a. No consent necessary. The data applied are not personal.

26b. NA

27. Confidentiality

The data will be treated with confidentiality as required by the data producers.

28. Declaration of interests

There are no potential conflicts of interests.

29. Access to data

The research team at NIPH will have access to the data. Data and statistical programming code can be made available upon publication of results. Data providers can, however, limit the coverage of the publicly available sales data due to business considerations.

30. Ancillary and post-trial care

Not applicable.

31. Dissemination policy

31a. Results from the trial will be communicated to the Norwegian Ministry of Health and Care, Vinmonopolet, the research community and the general public via various suitable outlets, including research reports in peer-reviewed scientific journals and media presentations.

31b. The research team at NIPH will author the papers presenting the trial results.

31c. The full protocol will be published. Statistical programming code and some of the data can be made public upon publication.

Appendices

Non-IRB applicability confirmation

Participant timeline

WHO dataset

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