Analytical Plan for efficacy of predetermined sounds as a hunting strategy in the luring of turkeys: randomized controlled trial

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Document version

Version	Alterations
01	Initial version

1 ABBREVIATIONS

- CI: confidence interval
- OR: odds ratio
- SD: standard deviation

2 CONTEXT

2.1 Objectives

To determine the efficacy of predetermined sounds as a hunting strategy in the luring of turkeys in rural areas of the United States.

2.2 Hypotheses

The hunter calls are effective in provoking a response from turkey individuals or groups.

3 DATA

3.1 Raw data

Upon study start the raw data will be collected in a raw table, that will be processed before analysis.

This dataset will include the dates, time of start and end of each attempt (defined in section 4.1), experimental condition (defined in 4.3), study outcome (section 4.4) and group size (section 4.5).

Each row represents all information collected from each study participant, and each participant included will require a unique study ID. The outcome should be recorded as a binary variable: either the attempt provoked a response (gobbles) or reached the end of

attempt without experiencing the event. This information can be recorded in either text form (eg, yes/no), or an indicator (response = 1, no response = 0).

Attempt length can be recorded in two ways, depending on the measuring tool: as the duration in minutes (if a timer/chronometer is used), or as separate times of start and end (when a clock is used).

Call type will be recorded as a categorical variable, if many types of calls are employed during the experiment. These will be aggregated into a binary variable for analysis.

The group size should be recorded as the count of animals confirmed to be present at the time of the attempt (this confirmation can be assessed after the encounter has been concluded, as it is assumed to be valid at the beginning of the encounter). If no encounter happens during the attempt, the group size should be left empty, or recorded as “NA”.

3.2 Analytical dataset

All variables in the analytical set were labeled according to the raw data provided and values were labeled according to the data dictionary for the preparation of production-quality results tables and figures.

4 STUDY PARAMETERS

4.1 Study design

This is a placebo-controlled randomized trial for determining the efficacy of hunter calls on provoking turkeys to gobble. The efficacy measure is defined as the probability of successfully receiving a turkey response after making a call or a set of calls.

It is assumed that (1) turkeys are present in the vicinity of the hunting party at the moment of a call being placed, (2) the turkeys can hear the calling attempts made by hunters and (3) the hunters can hear the turkey response, if a response is given (see Observations and Limitations). Confirmation of turkey presence at the time of the call may be ascertained at a later moment, if the hunting party engages with a turkey individual or group within a reasonable amount of time, when turkeys do not respond to the call.

Data collection will be performed in multiple locations, possibly in multiple states of the country, enabled by crowd-sourcing of volunteer groups that agree to follow the experiment guidelines. This imposes a hierarchical structure on the data, analogous to a multi-center clinical trial.

Attempts

The unit of measurement for this experiment will be defined as an attempt, a pre-specified period of time (in minutes) where the hunters either make a hunting call (test) or stay silent (control).

This period of time will be previously agreed upon by the relevant subject matter experts (experienced hunters), and all attempts should be kept as close as possible to this time specification, for increased accuracy of measurements and internal validity of the experiment. It is recommended that a timer or clock is used to ensure the attempt has been fully realized, and time of start and end of each attempt be recorded in a CRF or a notebook by the experimenter.

The hunters will decide when it is appropriate to start an attempt, when they have reason to believe in the presence of a turkey individual or group in the area (under the assumptions described above). The hunting party may make many attempts as they want during the hunting session or season, and there is no limitation on the number of attempts within a single day.

Randomization

Each attempt will be randomized to either test or control conditions. The test attempt is defined as an attempt where a call or multiple calls are made during the attempt duration. The (placebo-like) control condition will be silence for the duration of the attempt.

With only two experimental conditions, test and control, randomization will happen at the measurement level. As such, each attempt will be randomized to either test or control by using an electronic device (cell phone app, if available) or by tossing a coin.

4.2 Inclusion and exclusion criteria

N/A

4.3 Exposures

The exposure will be defined as a single attempt (defined in section 4.1) performed by the hunter(s) to provoke a response from the turkeys. When an attempt is started, the exposure will be randomized to test (exposed) or control (unexposed).

4.4 Outcomes

For the duration of each attempt (defined in section 4.1) the study outcome will be recorded as either a response or no response (see also section 3.1). It is known that turkeys may gobble at random and it is possible that it may happen without an attempt being performed; those responses will be recorded as part of the experiment as the unexposed (control) responses.

Specification of outcome measures (Zarin, 2011):

1. (Domain) Hunting
2. (Specific measurement) Turkey response to hunter calls
3. (Specific metric) End-value
4. (Method of aggregation) Odds of turkey response

Primary outcome

Odds of turkey response within the timeframe specified in the study protocol (to be determined).

4.5 Covariates

- group size (determined after the encounter, but recorded as valid at the moment the attempt started)

5 STATISTICAL METHODS

5.1 Statistical analyses

5.1.1 Descriptive analyses

The epidemiological profile of the study participants will be described. Demographic (sex and age) and clinical variables will be described as mean (SD) or as counts and proportions (%), as appropriate. The distributions of participants' characteristics will be summarized in tables and visualized in exploratory plots.

5.1.2 Inferential analyses

All inferential analyses will be performed in the statistical models (described in the next section).

5.1.3 Statistical modeling

The odds of a turkey individual or group responding to a call (section 4.4) will be estimated using a multivariate logistic regression and reported as an odds ratio between the attempts with the exposure and the attempts without the exposure (section 4.3). This probability will be adjusted by the group size, if available (section 4.5), to account for the effect of group density on the likelihood of a response when provoked by the call.

5.1.4 Missing data

Missing data will be assumed to be Missing At Random (MAR), when missingness in recorded data depend on variables that were not recorded (unobserved variables). In

particular it is assumed that the group size (observed variable) is dependent on the group presence (unobserved).

A missing data imputation approach will be performed with a multiple logistic regression, following the same specification defined in 5.1.3. This method creates a single dataset that represents the best estimate of what the missing data would look like, conditional on known frequencies observed in the data, and is recommended for simpler datasets.

Missing data counts and proportions will be reported in tables.

5.2 Significance and Confidence Intervals

All analyses will be performed using the significance level of 5%. All significance hypothesis tests and confidence intervals computed will be two-tailed.

5.3 Study size and Power

A rule of thumb of 10-20 measurements per variable can be used to choose a sample size for this experiment. With two variables included in the analysis a total of 20 to 40 attempts, randomly allocated into test/control should provide enough power to detect an effect.

5.4 Statistical packages

This analysis will be performed using the statistical software R (currently on version 4.3.3).

6 OBSERVATIONS AND LIMITATIONS

Assumption on turkey presence

Section 4.1 lists the assumptions required for the experiment:

1. turkeys are present in the vicinity of the hunting party at the moment of a call being placed;
2. the turkeys can hear the calling attempts made by hunters;
3. the hunters can hear the turkey response, if a response is given.

The main motivation for the usage of hunting calls is to try to identify the presence of turkeys in the area, but this also translates into the main limitation of the study: without knowing whether the animals are present, one cannot be sure the calls are effective in provoking their response.

The assumptions above simplify the events when a confirmation is possible (either before the call or after the hunting event is concluded). When a confirmation is not possible for an event, data will be recorded as missing, which may also bias the analysis. Nevertheless it is chosen that a single effect is being calculated for this efficacy analysis.

Measurement of group size

It will not be possible to count or estimate the group size when no encounter happens. This makes it harder to adjust the estimate for the effects by the group count or density. For this reason it will be considered a missing data imputation approach on the group size, after sufficiently large dataset is gathered (section 5.3).

It is hypothesized that larger groups (denser) will be more susceptible to respond, when provoked or at random as a natural behavior in the habitat. Any response without a call will contribute to the probability of unexposed responses. An efficacy conclusion will be drawn when the number of exposed responses is significantly larger than the number of unexposed responses.

Recommended reporting guideline

The EQUATOR network reporting guidelines (http://www.equator-network.org/) have seen increasing adoption by scientific journals. All clinical trials are recommended to be reported following the CONSORT guideline (Schulz K F, Altman D G, Moher D., 2010).

7 REFERENCES

- Zarin DA, et al. The ClinicalTrials.gov results database – update and key issues. N Engl J Med 2011;364:852-60 (https://doi.org/10.1056/NEJMsa1012065).
- Gamble C, et al. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. JAMA. 2017;318(23):2337–2343 (https://doi.org/10.1001/jama.2017.18556).
- Schulz K F, Altman D G, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials BMJ 2010; 340 :c332 (https://doi.org/10.1136/bmj.c332).

8 APPENDIX

This document was elaborated following recommendations on the structure for Statistical Analysis Plans (Gamble, 2017) for better transparency and clarity.

8.1 Associated analyses

This document is part of a larger project and is supported by other documents, linked below.

Study design for efficacy of predetermined sounds as a hunting strategy in the luring of turkeys in various locations: multi-center randomized controlled trial

https://philsf-biostat.github.io/SAR-2024-007-SS/

8.2 Availability

All documents from this consultation were included in the consultant's Portfolio.

The portfolio is available at:

https://philsf-biostat.github.io/SAR-2024-006-SS/