

Sample size for prediction of quantitative and binary outcomes based on cohort study

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For EPPIC_2021 application (PI Jean King. Project/Core PIs: Korkin, Ruiz).

Consider a cohort study of three groups: MBSR, acupuncture, and control, each has same sample size n . The total sample size is $3n$.

Predict quantitative outcome based on regression model assumptions

Sample size for prediction accuracy of quantitative outcomes based on simulations.

Consider a linear mixed effect model as the true underlying model:

$$Y_{ij} = \eta_{ij}(X) + \epsilon_{ij}$$

, where

$$\eta_{ij}(X) = \beta_0 + b_i + \beta_{acup} * acup_{ij} + \beta_{mbsr} * mbsr_{ij} + \beta_{sex} * sex_{ij} + \beta_{age} * age_{ij} + \beta_{edu} * edu_{ij} + \beta_{len} * len_{ij} + \beta_{base} * base_{ij} + \beta_{conc} * conc_{ij} + \sum_k \beta_k * x_{ijk}$$

and

$$b_i \sim N(0, \sigma_i^2) \quad \text{and} \quad \epsilon_{ij} \stackrel{iid}{\sim} N(0, \sigma^2).$$

Interpretation:

- Y_{ij} : quantitative response variable of pain reduction (i.e., TreatmentImpact, after a given period of time since the beginning of treatment) for the j th individual in the i th racial group. Positive value means pain reduces.
- β_0 : a "natural" pain reduction corresponds to no-treatment (no acupuncture nor MBSR) and all other covariates being 0.
- $b_i \sim N(0, \sigma_i^2)$: The mixed-effect (clustering effect) of the i th racial group. Individuals in the same racial group have the same b_i value so that their pair-wise covariance is σ_i^2 .
- $acup = 1$ if acupuncture treatment, $= 0$ o.w. β_{acup} is the effect of acupuncture.
- $mbsr = 1$ if MBSR treatment, $= 0$ o.w. β_{mbsr} is the effect of MBSR.
- $sex = 1$ if male, $= 0$ if female. β_{sex} is the effect of sex.
- age : standardized age value (mean 0 and sd 1). β_{age} is the effect of age.
- edu : education level: 0 / 1, 50% each.
- len : duration length of pain. short or long: 0 / 1, 50% each.
- bas : Baseline pain score. standardized.

- *conc*: presence of certain concomitant diseases: 0/1, 50% each.
- x_k : standardized value of the k th PainMarker, $k = 1, \dots, p$. β_k 's are the corresponding effects. They are from OMICS- and biopsychosocial PainMarkers.
- z_{lij} and z_{mij} are modifiers for acupuncture and MBSR, respectively. They are from OMICS- and biopsychosocial PainMarkers.
- The error SD σ can be used to adjust the relative effects (or signal-to-noise ratio) regarding β parameters, and the variation explained model (R^2).
- Cohen's

$$f^2 = R^2/(1-R^2) = \frac{\sigma_i^2 + \beta_{acup}^2 Var(acup) + \beta_{mbsr}^2 Var(mbsr) + \beta_{sex}^2 Var(sex) + \beta_{age}^2 Var(age) + \sum_{k=1}^p \beta_k^2 Var(x_k)}{\sigma^2}$$

, where R^2 is the coefficient of determination, the proportion of the variation in the dependent variable that is predictable from the independent variable(s).

Considerations:

- b_i : consider 3 groups, roughly equal numbers in the sample.
- β_{acup} , β_{mbsr} , β_{sex} , and β_{age} are used to set/control their R^2 , i.e., the percentage of variation explained by these "basic" factors.
- β_{sex} : Consider males are easier to reduce pain than females. Assume 50
- β_k , γ_l , γ_m are used to set the percentage of variation explained by these extra factors.
- Interaction terms are for Hypothesis 1 saying that the effects of treatments are "modulated by biopsychosocial factors".
- This study does address the aim of clustering patients ("Clustering and discovery of EPPIC-TreatmentPhenotypes" in Project 3). If some factors/markers are positively and some are negatively interacted with acupuncture/MBSR, then we could decide which treatment is better for them based on their markers. [Check Hong's project for AbbVie on subgrouping patients for drug treatment.]

Predict binary outcome based on logistic model assumptions

Consider a generalized linear mixed effect model as the true underlying model:

$$E(P(Y_{ij} = 1|X)) = \frac{1}{1 + \exp(-\eta_{ij}(X))},$$

where X is the matrix of covariate data, and $\eta_{ij}(X)$ is same as above (except that the coefficient values could be different)

Interpretation:

- Y_{ij} : binary response variable of TreatmentResponse for the j th individual in the i th racial group. 1 for pain relief, 0 for no relief.
- β_0 : the baseline pain relieve probability when no interventions and all other covariates being 0. Together with othe terms, we can adjust β_0 to control the prevalence of Y .
- We considered the ORs of some predictors based on Tables 2 and 3 of [?] "Patient characteristics and variation in treatment outcomes: which patients benefit most from acupuncture for chronic pain?"

Considerations:

We use AUC to measure how well the factors explains / contributes to the model. AUC and Cox and Snell R2 are connected (<https://onlinelibrary.wiley.com/doi/full/10.1002/sim.8806>). Both are used to represent

how well the factors explains the model (Cox and Snell R² is an extension of R² for measuring the percentage of variation explained in regression). Both are interchangeably used for calculating the minimum sample size based on the criterion regarding Nagelkerke's R-squared value. See The formula by given in Fig 5 of paper [?]: <https://www.research.manchester.ac.uk/portal/files/161373531/bmj.m441.full.pdf>

```
library(MASS);
library(nlme);
source("D:/WPI/prediction/Lib_Prediction.R");
source("D:/WPI/prediction/Lib_simu_genetic_data.R");
```

```
## Rlab 2.15.1 attached.
```

```
##
```

```
## Attaching package: 'Rlab'
```

```
## The following object is masked from 'package:MASS':
```

```
##
```

```
##      michelson
```

```
## The following objects are masked from 'package:stats':
```

```
##
```

```
##      dexp, dgamma, dweibull, pexp, pgamma, pweibull, qexp, qgamma,
```

```
##      qweibull, rexp, rgamma, rweibull
```

```
## The following object is masked from 'package:datasets':
```

```
##
```

```
##      precip
```

```
source("D:/WPI/prediction/generate_response_formula.R");
```

###Parameter setting

```
###Parameters on the effects / coefficients
```

```
beta0 = -0.5; #For binary trait, the risk at X=0 is 1/(1+exp(-beta0)). The average risk (prevalence)
# Y = array(NA, length(Xbeta));
# for (i in 1:length(Y)) {
#   Pylx = 1/(1 + exp(-Xbeta[i] - beta0)); # P(y=1 | x) based on logistic model
#   Y[i] = ifelse(runif(1) < Pylx, 1, 0);
# }
# mean(Y); #prevalance of Y.
```

```
#beta0 = -7; # for binary trait. Risk when X=0 is 1/(1+exp(7))=0.0009110512. Also, at the given coeff
#beta0 = -3; # for binary trait. Risk when X=0 is 1/(1+exp(3))=0.04742587. Also, at the given coeff
```

```
raceN = 3; #Number of racial groups
```

```
sigma.race = 1; #pair-wise covariance among individuals in the same racial group
```

```
beta.race = 1; #treat the "coefficient" of the mix-effect bi be 1.
```

```
beta.acup = log(4.9); #6; #Coeff of acupuncture
```

```
beta.mbsr = log(4.9); #6; #Coeff of mbsr
```

```
beta.sex = log(1.1); #1;
```

```
beta.age = log(1.25); #-1;
```

```
beta.edu = log(1.26); #1;
```

```

beta.len = log(1.13); #1;
beta.bas = log(0.80);#1;
beta.conc = log(0.77); #1;

markerN = 10; #The # of PainMarkers
beta.biom.v = 2; #1; #The value of the coeff of the biomarkers
beta.biom = rep(beta.biom.v, markerN); #Coeff of the biomarkers
names.xbiom = paste("xbiom", 1:markerN, sep=""); #variable names for biomarkers

mdfN.acup = 4; #The # of modifiers for acupuncture
beta.mdf.acup.v=2; #The value of the coeff of accupunctur's modifiers
beta.mdf.acup = rep(beta.mdf.acup.v, mdfN.acup); #Vector of coeffs of accupunctur's modifiers
gama.acup.v = 2; #The value of the coeff of the modifier*acupucture interaction terms.
gama.acup = rep(gama.acup.v, mdfN.acup); #Vector of coeffs of the modifier*acupucture interaction terms.

names.mdf.acup = paste("zmdfAcup", 1:mdfN.acup, sep=""); #variable names of the modifiers for acupunc

mdfN.mbsr = 4; #The # of modifiers for MBSR
beta.mdf.mbsr.v=2; #The value of the coeff of MBSR's modifiers
beta.mdf.mbsr = rep(beta.mdf.mbsr.v, mdfN.mbsr); #Vector of coeffs of accupunctur's modifiers
gama.mbsr.v = 2; #The value of the coeff of the modifier*MBSR interaction terms.
gama.mbsr = rep(gama.mbsr.v, mdfN.mbsr); #Vector of coeffs of the modifier*MBSR interaction terms.

names.mdf.mbsr = paste("zmdfMBSR", 1:mdfN.mbsr, sep=""); #variable names of the modifiers for MBSR

errSD=1; #The SD of error term

###Parametters on prodiction process
isRandomCV=T; #Random cross-validation in prediction
nfold=5; #The number of folds in cross-validation
nrepeat=2; #number of repeats of cross-validation

###Parameters on simulations
simuN = 100; #The number of simulations.

###Data simulation and prediction outcomes
predProp = c(0, 0.25, 0.5, 0.75, 1); #Proportion of true predictors besides names.basic that are incl
models = vector(mode = "list", length(predProp)); #prediction models .
outputs = vector(mode = "list", length(predProp)); #prediction outputs .

###Parameters on data
groupSampleSizes = seq(20, 400, by=20);
#groupSampleSizes = seq(500, 2000, by=100);
#groupSampleSizes = seq(150, 500, by=50);
AUC = array(NA, dim=c(length(groupSampleSizes), length(predProp))); #Store AUC over sample sizes and pr
for(gi in 1:length(groupSampleSizes)){
  groupSampleSize = groupSampleSizes[gi]; #sample size for each of the three groups: control, mbsr, and

###Looping through simulations
R2.controls = array(NA, simuN); #Store the R2 of the controlling predictors.
for(i in 1:simuN) {
  ###Generate data
  x0 = rep(1, groupSampleSize*3);

```

```

#The mixed-effect term for racial group
xrace = sample(1:raceN, size=groupSampleSize*3, replace=T, prob=rep(1/raceN, raceN));
  #Assume equal chance for each racial group to be sampled.
b.xrace = array(NA, dim=groupSampleSize*3); #b.xrace is the vector of b_i values.
for (racei in 1:raceN){ b.xrace[which(xrace==racei)] = rnorm(1, sd=sigma.race); }
  #assign the same b_i value for the all in the ith racial group.

#The "basic" factors
xacup = c(rep(0, groupSampleSize*2), rep(1, groupSampleSize)); #acupuncture group indicator
xmbsr = c(rep(0, groupSampleSize), rep(1, groupSampleSize), rep(0, groupSampleSize)); #MBSR group indicator
xsex = rbinom(n=groupSampleSize*3, size=1, prob=0.5); #50% recruited are males??
xage = rnorm(n=groupSampleSize*3, mean=0, sd=1); #standardized age.
xedu = rbinom(n=groupSampleSize*3, size=1, prob=0.5);
xlen = rbinom(n=groupSampleSize*3, size=1, prob=0.5);
xbas = rnorm(n=groupSampleSize*3, mean=0, sd=1);
xconc = rbinom(n=groupSampleSize*3, size=1, prob=0.5);

#PainMarker data
xbiom = data.frame(matrix(rnorm(n=groupSampleSize*3*markerN), ncol=markerN)); #Assume biomarker values
names(xbiom) = names.xbiom;

#acupuncture-modifier data
zmdfAcup = data.frame(matrix(rnorm(n=groupSampleSize*3*mdfN.acup), ncol=mdfN.acup)); #Assume acupuncture modifier data
names(zmdfAcup) = names.mdf.acup;

#mbsr-modifier data
zmdfMBSR = data.frame(matrix(rnorm(n=groupSampleSize*3*mdfN.mbsr), ncol=mdfN.mbsr)); #Assume mbsr modifier data
names(zmdfMBSR) = names.mdf.mbsr;

Xmatrix = cbind(x0, b.xrace, xacup, xmbsr, xsex, xage, xedu, xlen, xbas, xconc, xbiom, zmdfAcup, zmdfMBSR);

#### Generate response
names.mainEff = c("x0", "b.xrace", "xacup", "xmbsr", "xsex", "xage", "xedu", "xlen", "xbas", "xconc", "xbiom", "zmdfAcup", "zmdfMBSR");
coeffs.mainEff = c(beta0, beta.race, beta.acup, beta.mbsr, beta.sex, beta.age, beta.edu, beta.len, beta.bas, beta.conc, beta.biom, beta.acup, beta.mbsr);
names.trt = c("xacup", "xmbsr"); #variable names of the treatments
names.mdf = list(names.mdf.acup, names.mdf.mbsr); #variable names of the modifiers corresponding to the treatments
coeffs.interaction = list(gama.acup, gama.mbsr); #coefficients of the treatment-modifier interaction

# ####---Quantitative Response---
# resp = get.Y.reg(XData=Xmatrix, names.mainEff, coeffs.mainEff, names.trt, names.mdf, coeffs.interaction);
# #print(resp$R2); #proportion of variation explained by all predictors
#
# #Calculate the R^2 of the controlling predictors
# vars.control = c(varBeta0=0, varRace=sigma.race^2, varAcup=(1/3)*(1-1/3), varMbsr=(1/3)*(1-1/3), varSex=0.25, varAge=1, varEdu=0.25, varLen=0.25, varBas=1, varConc=0.25, varBiom=1, varAcupMbsr=0);
# betas.control = c(beta0, beta.race, beta.acup, beta.mbsr, beta.sex, beta.age, beta.edu, beta.len, beta.bas, beta.conc, beta.biom, beta.acup, beta.mbsr);
# R2.controls[i] = sum(vars.control*betas.control^2)/var(resp$Y);

####---Binary Response---
resp = get.Y.logit(XData=Xmatrix, names.mainEff, coeffs.mainEff, names.trt, names.mdf, coeffs.interaction);

####Combine data for analysis
xrace = as.factor(xrace); #Convert race into factor variable, which is used in data analysis.

```

```

dat = data.frame(Y=resp$Y, Xmatrix, xrace);

####Predictive analysis
names.control = c("xrace", "xacup", "xmbsr", "xsex", "xage", "xedu", "xlen", "xbas", "xconc"); #Con
names.trt.all = c("xacup", "xmbsr"); #All possible treatments that could have interaction effects.
for (mi in 1:length(predProp)){
  ##Create model formula based on proportion of predictors used.
  xbiom.used = round(length(names.xbiom)*predProp[mi]);
  mdf.acup.used = round(length(names.mdf.acup)*predProp[mi]);
  mdf.mbsr.used = round(length(names.mdf.mbsr)*predProp[mi]);
  names.main=c(names.control, names.xbiom[0:xbiom.used], names.mdf.acup[0:mdf.acup.used], names.mdf
  if (predProp[mi]==0) {
    names.trt = NULL;
  } else{
    names.trt = names.trt.all;
    names.mdf = list(names.mdf.acup[0:mdf.acup.used], names.mdf.mbsr[0:mdf.mbsr.used]);
  }
  models[[mi]]= formula.f.r(names.main=names.main, names.trt=names.trt, names.mdf=names.mdf, names.

  # ### ---- Predict quantitative outcome ----
  # #out = meanPredEvalCV.lme(fixed=models[[mi]]$fixed, dat=dat, randomf=models[[mi]]$random, mode
  # out = meanPredEvalCV.lme(fixed=models[[mi]]$fixed, dat=dat, randomf=NULL, model_R='lm', loopn=
  # outputs[[mi]] = rbind(outputs[[mi]], t(c(MSE=out[1], L2normRatio=out[2], LinormRatio=out[3], co

  ### ---- Predict binary outcome ----
  out = predEvalCV.glm(formula=models[[mi]]$fixed, dat=dat, nfold=nfold, nrepeat=nrepeat, isRandom
  #outputs[[mi]] = rbind(outputs[[mi]], t(c(prob=out[1], sensi=out[2], speci=out[3], AUC=out[4])));
  outputs[[mi]] = rbind(outputs[[mi]], t(unlist(out)));

}
}

# #True underlying model
print(c(sampleSize=groupSampleSize*3, raceN=raceN, sigma.race = sigma.race, beta.acup = beta.acup,
  beta.mbsr = beta.mbsr, beta.sex = beta.sex, beta.age = beta.age, beta.edu=beta.edu, beta.len=beta.l
  mdfN.acup=mdfN.acup, beta.mdf.acup.v=beta.mdf.acup.v, gama.acup.v=gama.acup.v,
  mdfN.mbsr=mdfN.mbsr, beta.mdf.mbsr.v=beta.mdf.mbsr.v, gama.mbsr.v=gama.mbsr.v));

# #R2 of controlling predictors
# mean(R2.controls);

#Prediction accuracies
for (mi in 1:length(predProp)){
  # print(predProp[mi]);
  # print(models[[mi]]$fixed);
  # print(apply(outputs[[mi]], 2, mean));
  # print(apply(outputs[[mi]], 2, quantile, probs=c(0.05, 0.95)));

  AUC[gi, mi] = apply(outputs[[mi]], 2, mean)[4];
}
}

```

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## Warning: glm.fit: fitted probabilities numerically 0 or 1 occurred
##      sampleSize      raceN      sigma.race      beta.acup      beta.mbsr
##      180.0000000      3.0000000      1.0000000      1.58923521      1.58923521
##      beta.sex      beta.age      beta.edu      beta.len      beta.bas
##      0.09531018      0.22314355      0.23111172      0.12221763      -0.22314355
##      beta.conc      markerN      beta.biom.v      mdfN.acup      beta.mdf.acup.v
##      -0.26136476      10.00000000      2.00000000      4.00000000      2.00000000
##      gama.acup.v      mdfN.mbsr      beta.mdf.mbsr.v      gama.mbsr.v
##      2.00000000      4.00000000      2.00000000      2.00000000
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##      sampleSize      raceN      sigma.race      beta.acup      beta.mbsr
##      300.00000000      3.00000000      1.00000000      1.58923521      1.58923521
##      beta.sex      beta.age      beta.edu      beta.len      beta.bas
##      0.09531018      0.22314355      0.23111172      0.12221763      -0.22314355
##      beta.conc      markerN      beta.biom.v      mdfN.acup      beta.mdf.acup.v
##      -0.26136476      10.00000000      2.00000000      4.00000000      2.00000000
##      gama.acup.v      mdfN.mbsr      beta.mdf.mbsr.v      gama.mbsr.v
##      2.00000000      4.00000000      2.00000000      2.00000000

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##      sampleSize      raceN      sigma.race      beta.acup      beta.mbsr
##      420.00000000      3.00000000      1.00000000      1.58923521      1.58923521
##      beta.sex      beta.age      beta.edu      beta.len      beta.bas
##      0.09531018      0.22314355      0.23111172      0.12221763      -0.22314355
##      beta.conc      markerN      beta.biom.v      mdfN.acup      beta.mdf.acup.v
##      -0.26136476      10.00000000      2.00000000      4.00000000      2.00000000
##      gama.acup.v      mdfN.mbsr      beta.mdf.mbsr.v      gama.mbsr.v
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##	sampleSize	raceN	sigma.race	beta.acup	beta.mbsr
##	480.00000000	3.00000000	1.00000000	1.58923521	1.58923521
##	beta.sex	beta.age	beta.edu	beta.len	beta.bas
##	0.09531018	0.22314355	0.23111172	0.12221763	-0.22314355
##	beta.conc	markerN	beta.biom.v	mdfN.acup	beta.mdf.acup.v
##	-0.26136476	10.00000000	2.00000000	4.00000000	2.00000000
##	gama.acup.v	mdfN.mbsr	beta.mdf.mbsr.v	gama.mbsr.v	
##	2.00000000	4.00000000	2.00000000	2.00000000	

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##	sampleSize	raceN	sigma.race	beta.acup	beta.mbsr
##	540.00000000	3.00000000	1.00000000	1.58923521	1.58923521
##	beta.sex	beta.age	beta.edu	beta.len	beta.bas
##	0.09531018	0.22314355	0.23111172	0.12221763	-0.22314355
##	beta.conc	markerN	beta.biom.v	mdfN.acup	beta.mdf.acup.v
##	-0.26136476	10.00000000	2.00000000	4.00000000	2.00000000
##	gama.acup.v	mdfN.mbsr	beta.mdf.mbsr.v	gama.mbsr.v	
##	2.00000000	4.00000000	2.00000000	2.00000000	

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##      sampleSize      raceN      sigma.race      beta.acup      beta.mbsr
##    660.00000000     3.00000000     1.00000000     1.58923521     1.58923521
##      beta.sex      beta.age      beta.edu      beta.len      beta.bas
##    0.09531018     0.22314355     0.23111172     0.12221763     -0.22314355
##      beta.conc      markerN      beta.biom.v      mdfN.acup      beta.mdf.acup.v
##   -0.26136476     10.00000000     2.00000000     4.00000000     2.00000000
##      gama.acup.v      mdfN.mbsr      beta.mdf.mbsr.v      gama.mbsr.v
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## -0.26136476      10.00000000      2.00000000      4.00000000      2.00000000
##      gama.acup.v      mdfN.mbsr      beta.mdf.mbsr.v      gama.mbsr.v
## 2.00000000      4.00000000      2.00000000      2.00000000

cbind(groupSampleSizes*3, AUC);

##      [,1]      [,2]      [,3]      [,4]      [,5]      [,6]
## [1,] 60 0.5143349 0.5771510 0.6273093 0.6889238 0.7141487
## [2,] 120 0.5156111 0.6111901 0.6795221 0.7159773 0.7933369
## [3,] 180 0.5134444 0.6283079 0.7089777 0.7535443 0.8321439
## [4,] 240 0.5139387 0.6397943 0.7276029 0.7827725 0.8517904
## [5,] 300 0.5141550 0.6485060 0.7404879 0.8024310 0.8647701
## [6,] 360 0.5144017 0.6553027 0.7498499 0.8165861 0.8740348
## [7,] 420 0.5146894 0.6598979 0.7570961 0.8271466 0.8813600
## [8,] 480 0.5158860 0.6638646 0.7630217 0.8358563 0.8887946
## [9,] 540 0.5173822 0.6677132 0.7680617 0.8430739 0.8961311
## [10,] 600 0.5184149 0.6711423 0.7724115 0.8490495 0.9032198
## [11,] 660 0.5189159 0.6737743 0.7761010 0.8541008 0.9098655
## [12,] 720 0.5198920 0.6763402 0.7791030 0.8583985 0.9157751
## [13,] 780 0.5204617 0.6785446 0.7817520 0.8621630 0.9208881
## [14,] 840 0.5208830 0.6804655 0.7842274 0.8654273 0.9253790
## [15,] 900 0.5217651 0.6824761 0.7865324 0.8683573 0.9293058
## [16,] 960 0.5224487 0.6841449 0.7884609 0.8709108 0.9327642
## [17,] 1020 0.5227664 0.6853927 0.7902140 0.8731390 0.9358521
## [18,] 1080 0.5232410 0.6866808 0.7917386 0.8751194 0.9386268
## [19,] 1140 0.5236824 0.6877997 0.7931733 0.8769214 0.9410994
## [20,] 1200 0.5240804 0.6888953 0.7945829 0.8786635 0.9433633
```